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 35.96 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, 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.
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 (Srinagarind 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 Scales 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.

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. In this study, the original Thai monosyllabic word lists (RAMA.SD-1) containing five lists of 25 monosyllabic words were used.

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

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
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-5L) version is a general health status questionnaire for children and adolescents. The questionnaire evaluates the four 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 patient's own rating of health is used to make a vertical VAS, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'.

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.23

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

| Table 2 | Audiological outcomes |
|---------|----------------------|
|         | Preoperative | 3 months | Mean difference (95% CI) | P value† | Preoperative | 12 months | Mean difference (95% CI) | P value† |
| Pure tone average | (n=144) | (n=144) | Better ear | 95.53±20.68 | 34.14±13.93 | 61.39 (57.39 to 65.40) | <0.001* | 96.10±22.05 | 31.87±12.71 | 64.23 (59.81 to 68.65) | <0.001* |
| SRT | (n=58) | (n=58) | Better ear | 86.72±24.11 | 37.47±17.00 | 49.26 (42.28 to 56.24) | <0.001* | 90.42±21.47 | 34.45±11.54 | 55.96 (49.50 to 62.42) | <0.001* |
| Speech discrimination score | (n=39) | (n=39) | Better ear | 28.82±34.83 | 47.33±32.92 | −18.51 (−27.13 to −9.90) | <0.001* | 29.76±35.39 | 62.24±28.51 | −32.47 (−43.00 to −21.94) | <0.001* |
| CAP score | (n=147) | (n=147) | 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* |

*Statistically significant.
†paired t-test.
CAP, categories of auditory performance; SRT, speech recognition threshold.
### Table 3  Quality of life outcomes

|                           | 1 month                      | 3 months                     | MD (95% CI) | P value† | 1 month                      | 12 months                     | MD (95% CI) | P value† |
|---------------------------|-----------------------------|------------------------------|-------------|----------|-----------------------------|------------------------------|-------------|----------|
| **EQ-5D-5L**              |                             |                              |             |          |                             |                              |             |          |
| Mobilty                   | 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 significant.†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.
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 $\chi^2$ 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 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   |
RESULTS

Patient’s demographics
There were 458 patients in this study, of whom, 220 were male and 238 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 postoperatively (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) (Table 3).

Factors contributing to the success
The effect of factors including the age, sex, onset of deafness, 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. 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. 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.

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.

### Table 5 Complications

| Complications | N=465 | %  |
|---------------|-------|----|
| 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 | 9    | 1.93 |
| Meningitis    | 9     | 1.93 |
| Electrodes dislodge | 8    | 1.72 |
| Implant migration/extrusion | 7    | 1.51 |
| Device failure | 19    | 4.09 |

**Table 5 Complications**

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2. No or little benefit from hearing aids.
3. SDS <50%.
4. The onset of deafness should not be >10 years.
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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