

# Surgical and functional outcomes of cochlear implantation in post-lingual and cross-over patients: First 5-year review of the National Ministry of Health Malaysia cochlear implant programme

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## SUMMARY

**Introduction:** There has been a paradigm shift in the management of acquired sensory neural deafness in the past 30years. This is due to the emergence of implantable hearing devices such as the cochlear implant. The objective of this study is to identify surgical and functional outcomes of post-lingual and cross-over patients implanted with a cochlear implant under the National Ministry of Health Cochlear Implant (CI) Program between 2009-2013.

**Materials and Methods:** We retrospectively reviewed all postlingual and cross-over recipients of cochlear implants under the National Ministry of Health CI Programme from 2009 to 2013. The outcomes measured were surgical complications and functional outcome. Surgical complications were divided into major and minor complications. Functional outcomes were measured using Categorical Auditory Performances (CAP) scale.

**Results:** A total of 41 post-lingual and 15 cross-over patients were implanted between 2009 and 2013. The age of implantees ranged from 3.6 years to 63.2 years old. There were two major complications (3.6%), one is a case of electrode migration at three months post implantation, and six months post second implantation. Another was a case of device failure at about one-year post implantation. Both patients were reimplanted in the same ear. There was no minor complication. The CAP score for both groups (overall) showed significant improvement with 96.4% achieved CAP score of five and above at 24 months after implantation ( $p < 0.001$ ). The CAP score showed marked improvement at the first 6 months post implantation and continued to improve with time in both groups.

**Conclusion:** The Malaysian National Ministry of Health Cochlear implant (CI) Program between 2009-2013 has been

a successful programme with good surgical and functional outcomes among the post lingual and cross-over patients.

## KEY WORDS:

*Cochlear implant - Postlingual Deafness - Complications - Surgical Outcomes-Functional Outcomes-Category of Auditory Performance (CAP)*

## INTRODUCTION

The first Food and Drug Administration (FDA) approved cochlear implant (CI) was produced in the 1980's.<sup>1</sup> Based on FDA information, approximately 324,200 people worldwide have received cochlear implants as of December 2012.<sup>2</sup> The device was first used for deaf adults and eventually was used on children.

In Malaysia, the first cochlear implant was performed in 1995 at Hospital University Kebangsaan Malaysia. Subsequently other local universities, like University Sains Malaysia and University of Malaya started their own cochlear implant programme. In 2008, the Malaysian Ministry of Health Cochlear Implant programme was formed. The aim of this team was to start a cochlear implant programme within the framework of the Ministry of Health to reach out to citizens throughout Malaysia who might benefit from a cochlear implant. In Malaysia, a total of seven hospitals were initially selected as cochlear implant centres (satellite hospitals). A Cochlear Implant Service Operational Policy (SOP) was developed to ensure consistent and professional standards of practice were delivered in all the Ministry of Health hospitals.<sup>3</sup>

Candidates were selected through a rigorous multidisciplinary assessment by surgeons, audiologists, speech therapists, paediatricians, radiologists, medical social

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Table I: The Categories of Auditory Performance Score<sup>7</sup>

Category	Categorical Auditory Performances (CAP) Criteria
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 of common phrases without lip-reading
6	Understanding of conversation without lip-reading
7	Use of telephone with known listener

Table II: Descriptive statistics of CAP score for Postlingual and Cross-Over Group

CAP Score at 6months	Number of patients	Percentage (%)
1	1	1.8
2	2	3.6
3	1	1.8
4	10	17.9
5	20	35.7
6	16	28.6
7	6	10.7
CAP Score at 12months		
0	1	1.8
4	4	7.1
5	15	26.8
6	21	37.5
7	15	26.8
CAP Score at 24months		
0	1	1.8
4	1	1.8
5	10	17.9
6	22	39.3
7	22	39.3

welfare officers, psychologists, occupational therapists and other relevant professionals. Approval was done at a central committee meeting held at regular intervals. This committee included advisors from Hospital University Kebangsaan Malaysia (HUKM), Hospital Sains Malaysia (HUSM) and University Malaya Medical Centre (UMMC).

Surgeries were performed using a standard technique of cortical mastoidectomy via a post auricular incision followed by posterior tympanotomy. The electrodes were introduced either through a cochleostomy or round window approach.

We report here the outcomes of cochlear implantation among postlingual and crossover patients measuring surgical and functional outcomes and identifying areas which require further attention or improvement. The outcomes of prelingual recipients of cochlear implants under the National CI Programme is discussed elsewhere in a different article.

## MATERIALS AND METHODS

All postlingual and cross-over recipients of cochlear implants under the National Ministry of Health CI Programme from 2009 to 2013 were included in this review which included 41 postlingual and 15 cross-over patients. Data was obtained from the National ORL Registry of Hearing and Otology Related Disease/Cochlear Implant. Additional information

was acquired from the satellite hospitals. The cochlear implants used were from Med-El® and Cochlear®. Post-lingual recipients are patients who already have well-developed spoken language skills before implantation whereas cross-over recipients are patients who have only developed some degree of spoken language before implantation.<sup>4</sup> The outcomes measured were surgical complications and functional outcomes.

A surgical complication is defined as an unwanted event related to the surgery causing morbidity or requiring an additional surgical procedure. The complications were divided into major and minor complications. An event was documented as a major complication if surgery resulted in a significant medical problem, required additional major surgery or resulted in permanent disability. Other complications not related to the above were considered minor complications and these include wound infection, delayed wound healing which do not need surgical intervention and transient facial paresis.<sup>5,6</sup>

Functional outcome was measured using the Categorical Auditory Performances (CAP) scale (Table I). The CAP is a global outcome measure of auditory receptive abilities; the lowest level describes no awareness of environmental sounds, and the highest level is represented by the ability to use the telephone with a known speaker.<sup>7</sup>

## RESULTS

In total there were 56 implantees with 41 postlingual cochlear implant patients and 15 cross-over patients in the period between 2009 and 2013. In which 29 were male and 27 were female. In terms of ethnicity, Malays were the majority (78.6) followed by Chinese (10.7), Indian (8.9) and others (1.8). The age of implantees ranged from 3.6 years to 63.2 years old. Indication for cochlear implantation was bilateral severe to profound progressive sensorineural hearing loss. Majority of them were idiopathic (36 patients). Others were trauma (nine patients), meningitis (five patients), ear related disease (four patients) and familial (two patients).

In our series, there was no mortality. There were two major surgical complications, one is a case of electrode migration at three months post first implantation, and six months post second implantation. Another case was a device failure at about one-year post implantation. Both patients were reimplanted in the same ear. There was no minor complication.

As for functional outcome, Categorical Auditory Performances (CAP) score was measured prior to implantation at 6, 12 and 24 months post implantation. The implantees were grouped according to cross-over and post lingual group. Pre-implantation mean CAP score was 0 for both groups. At 24 months post implant, 96.4% of our implantees were able to understand common phrases without lip reading (CAP score 5 and above) irrespective of age of implant. Twenty-two implantees (39.3%) were able to use the telephone with a known listener. The CAP score for both groups (overall) showed significant improvement with 78.6% achieved CAP score of 6 and above at 24 months after implantation ( $p < 0.001$ ) (Table II).

The CAP score showed marked improvement at the first six months post implantation and continued to improve with time in both groups. The post lingual group showed improvement in CAP score better than the cross-over group within six and 12 months of implantation but not statistically significant ( $p = 0.069$ ) after age adjustment.

## DISCUSSION

Sensory neural deafness can often be successfully habilitated with hearing-aids if the impairment is mild or moderate. However, in severe to profound sensory neural hearing loss, the amplification provided by hearing aids may be inadequate. Cochlear implant is a successful technology which has been used to rehabilitate this group of patients.<sup>8</sup> For the cross-over group of patients, who are in the paediatric age group, this device enables normal speech and language development and optimises their potential in academic achievement. On the other hand, post lingual group of patients, most of whom are adults, hearing deprivation can severely impact their social life and working environment without auditory intervention.<sup>9</sup>

In this study of postlingual and cross-over group, there was no mortality. There were two major complications, one is a case

of electrode migration at three months post first implantation, and 6 months post second implantation. Another case involved device failures at about one-year post implantation. Both patients were reimplanted in the same ear. There was no minor complication. The particular case involving electrode migration cannot be explained satisfactorily because it occurred twice in the same patient, using the same electrode. This could be due to electrode rejection. The patient was successfully reimplanted using another specially designed electrode (*FORM* electrode by *Med-El*). The overall surgical complication in our program is low and it is comparable with other large series which report complication rates of 5–30%.<sup>10-14</sup>

The type of incision used for the surgery was a retroauricular 'C' shaped incision measuring 5-6 cm. There was no major skin complication noted. While it has been proposed that wider incisions reduce skin complication rates, we found that a standard retroauricular incision to be adequate as well.<sup>15</sup> We believe that our surgical technique of avoiding big surgical flaps, the usage of facial nerve monitor in all cases and the practice of supervised cochlear implant surgeries by senior experienced otology surgeons have contributed in minimizing the complications.

From our study, CAP (Categorical Auditory Performances) was used as a method in measuring the functional outcome of Cochlear implant in postlingual and cross-over patients. This method of measuring functional outcome have been widely used world-wide as there is good inter-observer reliability and can be used across wide age groups.<sup>16</sup> The CAP score showed marked improvement at the first six months post implantation with continued improvement in subsequent months. Similar to other studies conducted on post-lingual patients, the marked improvement occurs especially during the first six months after implantation.<sup>4,17</sup> Post lingual patients are also considered better candidates for implantation because more activation of auditory associated brain activity happens in postlingual patients as shown in the study conducted by Goma Nahla et al.<sup>18</sup>

Life expectancy has been increasing in Malaysia. Based on the report released by the Malaysian statistic department in October 2016, life expectancy of Malaysian population in 2016 was 74.7 compared to 1980 in which the life expectancy was only 67.4.<sup>19,20</sup> The increase in life span and productivity of Malaysians are reflected in the increase of the minimum retirement age of an employee from 55 to 60 years based on the Minimum Retirement Age Act 2012 which was gazetted on 16 August 2012 and was enforced on 1 July 2013.<sup>21</sup> The good outcomes of cochlear implantation for adults noted in this study shows that working or socially active adults with severe to profound SNHL can obtain good auditory benefits from a cochlear implant.

## CONCLUSION

This review of post lingual and cross-over cochlear implant patients from the National Ministry of Health Cochlear Implant Programme shows that cochlear implant surgery is a safe surgical procedure with good surgical and functional outcomes. Surgical complication rates were less than 5% in

our tour series with two major complications and no minor complications. The majority of implantees have significantly gained auditory improvement as shown by the CAP scores. Postlingual and cross-over implantees require a shorter duration of rehabilitation period and marked improvement of auditory performance is seen in six months.

## RECOMMENDATIONS

1. To provide continuous training for members in the CI team to ensure that the programme is up to date and conform to international standards of practice.
2. To do a more robust study in future regarding the factors contributing to the outcome of Cochlear Implant programme.
3. Staffing: Adequate numbers of personnel in the satellite hospitals which include Surgeons, Audiologists, Speech Therapists and trained paramedics to ensure optimum service delivered to patient.
4. To create awareness among the health care workers and public in general regarding the availability of such services in certain hospitals under Ministry of Health Malaysia.
5. To develop a suitable national assessment tool in audiological and speech outcomes according to the needs of the local population.
6. To collaborate with other agencies and universities which have vast knowledge and experiences on cochlear implantations like Universiti Kebangsaan Malaysia, University of Malaya, Universiti Sains Malaysia.

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