Analysis of paediatric cochlear implant candidacy: Single centre, retrospective observational study

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ABSTRACT

Introduction: The criteria for cochlear implantation can differ among countries or even among regions in the same country. Patient selection is important for the identification of those children who can benefit the most from cochlear implants. A number of patients who are possible cochlear implant candidates do not meet the assessment criteria; and some of these requirements are modifiable components.

Materials and Methods: This single-centre, cross-sectional study used secondary data from 2014 until 2018. A consecutive sampling method was applied and a final sample size of 73 samples was achieved. Potential prelingual hearing loss candidates for cochlear implant aged less than 48 months old in Raja Permaisuri Bainun Hospital (HRPB), Ipoh Perak were included in this study. The candidacy selection outcome was analysed and reported as proportions. The associations between the evaluation criteria and outcome were examined using regression analysis.

Results: Of the 73 potential candidates, only 17 (23%) were selected to receive cochlear implants. Bivariate analysis identified hearing compliance, behaviour, medical contraindications and family commitment as significantly associated with cochlear implant evaluation outcome. However, multivariate logistic regression revealed only family commitment as a significant predictor of the outcome of the implant candidacy evaluation (OR 44.7; 95%CI 3.11–643.4; p<0.005).

Conclusion: Family commitment, a modifiable element, was the key factor affecting the selection of candidates. Addressing the reasons for this effect could increase the number of potential candidates who ultimately receive implants.

KEYWORDS:
cochlear, implant, candidacy selection, paediatric, family commitment

INTRODUCTION

Approximately 466 million people worldwide suffer from hearing loss, and many of these (34 million) are children.[1] Disabling hearing loss in children is defined as a hearing loss greater than 30dB in the better hearing ear. Hearing loss can be attributed to a number of factors, such as hereditary conditions, birth defects, infectious disorders, chronic ear infections, drug abuse, exposure to unnecessary noise and aging. The World Health Organization (WHO) estimates that about 60% of childhood hearing loss could be eliminated by preventive measures. When the circumstances are inevitable, interventions are required to ensure that children reach their full potential.[2]

Children's hearing is crucial for their understanding of spoken language and for academic achievements and social participation;[3,4] therefore, hearing loss is a serious obstacle to both education and social integration. Prelingual hearing loss has a detrimental impact on all aspects of language learning, but the influence is most profound on phonology, morphology, advanced vocabulary and syntax.[5] For this reason, children with hearing loss can benefit immensely from detection early in life, before the age of 6 months, and from receiving targeted interventions.[6,7] The recommended intervention plans include family counselling, hearing aid fittings, audio training, language learning and educational programs based on the needs and abilities of the infant or child.[8]

One study has shown that hearing-impaired children who receive appropriate and early hearing aid assessment and fitting at 3 months of age, followed by cochlear implantation at 9 months of age, will achieve normal language development in up to 96% of the cases.[9] Previous research in Malaysia determined that paediatric cochlear implantees under the age of 4 years showed better long-term results in terms of ability to communicate orally and to attend mainstream education compare to older age at implantation.[10] Children with severe and profound hearing loss benefit the most from cochlear implants in terms of speech comprehension and language development.[11]

Since December 2012, a total of 324,200 cochlear implants have been implanted worldwide. Approximately 58,000 adults and 38,000 children were implanted in the United States of America.[12] Between 2008 and 2018, a total of 380 cochlear implants were performed in Malaysia in 283 prelingual deaf children.[13] The interdisciplinary approach recommended by the NICE Guideline is the current standard of care for the selection of implant candidates.[14] A decision on the candidacy is reached by subjecting the child to medical, audiological and speech–language assessments. In addition,

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successful cochlear implant outcomes also require a number of steps that range from adequate preoperative amplification with hearing aids to uncomplicated surgery.

In Malaysia, cochlear implant candidates are chosen through a comprehensive multidisciplinary evaluation by the Satellite Hospital Committee, with final approval decided by the National Ministry of Health Cochlear Implant Committee at meetings held at regular intervals. The satellite committees are divided into the North, Central, South, East, Sarawak and Sabah zones. Every satellite committee consists of surgeons, audiologists, speech therapists, paediatricians, radiologists, medical social services officers, psychologists, occupational therapists and other related professionals. All potential implant candidates are evaluated by the Satellite Committee, and only those candidates who meet the selection requirements are sent to the National Cochlear Implant Committee for approval. The selection is based on the parameters set out in the Operational Policy of the Otorhinolaryngology Service.[15] Each child must be assessed from a variety of perspectives, including their physical, neurophysiological, physiological, audiological and family aspects.

One study found that about 70% of countries have national or local guidelines in place that regulate the candidacy for implantation. Another 20% have guidelines, but whether a patient is a candidate for implantation is decided by the individual clinical team. The remaining 10% of countries have no guidelines in place.[16]

In Malaysia, candidates for cochlear implants are chosen based on certain selection criteria. However, a number of patients who are potential cochlear implant candidates do not meet these criteria. The aim of this study was therefore to explore these candidate selection criteria and the factors that can affect the selection outcome. Recognising the attributes of failed candidacy selection may enable the establishment of effective strategies targeted at these factors, thereby increasing the number of suitable candidates.

MATERIALS AND METHODS

Study design

This was a single-centre, cross-sectional analysis using secondary data from 1 January 2014 to 31 December 2018. The data were taken from the minutes of the Satellite Committee meeting and from the Otorhinolaryngology (ENT) clinical records. Data on the decision of the candidacy selection and assessment of each selection criterion for cochlear implants were captured. Data capture was achieved using a structured checklist (see Appendix 1).

Study population and study sample

The study included candidates with prelingual hearing loss who were less than 48 months of age. The study population consisted of candidates for cochlear implant evaluation at Raja Permaisuri Bainun Hospital (HRPB). HRPB is one of the cochlear implant referral centres in the Northern Region of Malaysia. Candidates who were eligible for a second implant and with a pending selection decision by the Cochlear Implant Satellite Hospital Committee were excluded. Any candidates who had been transferred to another hospital for continued treatment were also excluded, as this would have had an effect on the findings. A consecutive method of sampling was used. In total, 73 candidates were eligible and were included.

Evaluation criteria for cochlear implants in HRPB (adopted from the Cochlear Implant Service Operational Policy Malaysia 2017)[15]

Candidacy evaluation is critical for determining the suitability of the patient for cochlear implantation. The eligibility evaluation for paediatric cochlear implantation was based on the following components:

a) Age of the candidate

In Malaysia, the prelingual child should be implanted before the age of 48 months, according to the cochlear implant guideline. Govaerts and colleagues (2002) showed that implantation before the age of 4 years seemed crucial to prevent permanent loss of auditory output.[17] Applicants in this age group therefore fulfilled the age criterion.

b) Audiology

The audiology assessment is used to define the current aural condition and to set a benchmark for aural rehabilitation after cochlear implantation. It consists of a pure tone audiometry assessment, a hearing aid compliance assessment and a sound-field threshold. Generally, the pure tone audiometry was conducted to ensure that candidates had a hearing loss at a level of 70 dB or higher. According to current US Food and Drug Administration guidelines, the indication for cochlear implantation is a bilateral profound sensorineural hearing loss (> 90dB) in children aged 9–24 months and a severe (70-85dB) to profound hearing loss in those aged 2–17 years.[18] A paediatric candidate also had to undergo a hearing aid testing period of at least 3 months prior to cochlear implantation.[19] The candidate needed to comply with wearing the hearing aid for at least 8 hours a day. Compliance with the wearing of a hearing aid was determined by a review of the data logging that was integrated into the hearing aid to track the average hours of use every day.

c) Speech and Language

Speech and language assessment is used to evaluate any progress in speech and language skills with the continued use of hearing aids during the trial period. Candidates receive stimulus response training (home-based program) consisting of a series of hearing (listening) exercises and lessons, receptive language (comprehension), expressive language (what the child says), speech (how the child speaks), pragmatics (social communication) and comprehension (perception). Appropriate behaviour towards stimulus–response training should be demonstrated. The behaviour of the candidates would then be classified as appropriate or inappropriate by the speech therapist. The training was customised to suit the individual needs of the candidate. Parental interaction with the home-based program was also assessed in various ways, such as by completion of homework and enhancement of the child's speech performance and learning behaviour.

Table I: Demographics of candidates for the Cochlear Implant Candidacy Evaluation

Characteristic	Frequency (%) (n=73)
Age (month), Mean (SD)	25.4±10.76
0-12 months	13 (17.8)
13-24 months	21 (28.8)
25-36 months	24 (32.9)
37-48 months	15 (20.5)
Gender	
Male	46 (63.0)
Female	27 (37.0)
Candidacy selection	
Selected	17 (23.3)
Rejected	56 (76.7)

Table II: Aided response by using hearing aids at low and high frequency

Aided response	High Frequency		Low Frequency	
	n	(%)	n	(%)
No response	14	(18.9)	16	(21.9)
Response out of speech range	44	(60.3)	32	(43.8)
Response in speech range	7	(9.6)	17	(23.3)
Defaulted	8	(11.0)	8	(11.0)

Table III: Medical and anatomical contraindications for cochlear implant surgery

Contraindications	Frequency (%) Total= 73
Medical	
Absolute	18 (24.7)
Relative	1 (1.4)
Mixed (Absolute & Relative)	4 (5.5)
No	50 (68.5)
Anatomical	
Absolute	5 (6.8)
Relative	9 (12.3)
Defaulted	13 (17.8)
No	46 (63.0)

Table IV: Absolute and Relative Medical contraindications for cochlear implant surgery

Medical Contraindications*	Frequency (%)
Absolute	
Global Developmental delay	
- Brain/Spine malformation	14 (63.6)
- Genetic	6 (27.3)
- Brain infection	2 (9.1)
Relative	
Medical conditions	1 (20)
Epilepsy	4 (80)
Anatomical contraindication*	
Absolute	
Cochlear nerve aplasia	2 (40)
Cochlear aplasia	3 (60)
Relative	
Cochlear nerve hypoplasia	5 (50)
Cochlear hypoplasia	5 (50)

*Subjects are possible to have more than one contraindication.

Table V: Factors associated with the Cochlear Implant candidacy selection outcome (using bivariate and multivariate analysis regression analysis)

Variable	Crude OR (95% CI)	p-value*	Adjusted OR (95% CI)	p-value
Gender				
Male	**Reference**		**Reference**	
Female	0.44 (0.13-1.53)	0.2	0.25 (0.01-3.41)	0.3
Hearing compliance				
No	**Reference**		**Reference**	
Yes	26.8 (6.4-115.03)	<0.01	8.8 (0.44-174.4)	0.15
Behaviour				
Inappropriate	**Reference**		**Reference**	
Appropriate	31.16 (3.84-253.08)	0.001	6.32 (0.42-94.43)	0.18
Medical contraindications				
No	**Reference**		**Reference**	
Yes	0.09 (0.01-0.78)	0.028	0.27 (0.01-5.44)	0.39
Anatomical contraindications				
No	**Reference**		**Reference**	
Yes	0.14(0.02-1.2)	0.07	0.07 (0.001-3.32)	0.17
Family commitment				
No	**Reference**		**Reference**	
Yes	112 (12.79-980.89)	<0.01	44.73 (3.11 – 643.4)	0.005

*p value <0.25 was taken to include the variables in the multivariate logistic regression analysis.

d) Medical considerations

Medical assessment is carried out with the aims of facilitating the selection of patients, of establishing realistic expectations and of developing an effective recovery plan. Absolute contraindications can include severe global developmental delay, extreme mental retardation to co-operate with speech training, acute or chronic otitis media and mastoiditis without disease eradication. Other medical problems, such as respiratory, cardiac and haematological problems or untreated epilepsy, served as relative contraindications.[20]

e) Anatomical considerations

Preoperative assessment of the cochleovestibular anatomy was performed in all candidates. The goal was to determine the presence of cochleovestibular defects that inhibit implantation. Absolute contraindications for the implant were cochlear nervous aplasia and/or cochlear aplasia, whereas the relative contraindications were cochlear nervous hypoplasia and/or cochlear hypoplasia.[21]

f) Family

The family was briefed by the clinical team regarding the results of the cochlear implant assessment and was given a thorough description of the cochlear implant procedure. The adherence to clinical appointments was also assessed by the clinical team. Families or candidates should be well motivated and willing to engage in the medical appointments that are required for the optimum use of the device.

Statistical analysis

The prevalence of candidates selected to receive a cochlear implant and the descriptive analysis of the independent variables were reported as proportions. We performed univariate and multivariate logistic regression analyses using SPSS 20.0 software. Odds ratios (OR) were reported with their respective 95% confidence intervals (CI), and values of $P < 0.05$ were considered statistically significant.

RESULTS

Demographic characteristics of candidates for cochlear implant candidacy evaluation

A total of 87 candidates were assessed by the HRPB Cochlear Implant Satellite Hospital Committee during the study period. Only 73 candidates were deemed eligible for the study. Among these, 17 (23.3%) candidates were ultimately selected to receive a cochlear implant. The mean age of the candidates was 25 months (SD±10.76), and most of them were males (67%) and their demographic characteristics are shown in Table I.

Severity of hearing loss

All candidates had profound or severe hearing loss in either the right or the left ear. 68.5% of the participants had a profound hearing loss in the right ear and 74.0% in the left ear. Similarly, 27.4% of the candidates had severe hearing loss in the right ear and 20.5% in the left ear. Overall, 3 candidates demonstrated an improvement in their hearing and were removed from the selection process.

Hearing aid use and the aided response using hearing aids at low and high frequency

Overall, 67.1% of the subjects were not compliant in wearing their hearing aid, 30.1% were compliant and 2.7% of the subjects defaulted in their follow-up appointment at the audiometry clinic. Table II shows that the aided response at high or low frequency mainly fell outside the speech range. The aided response of the candidates either fell outside the speech range or no response was seen at high or low frequency.

Speech and language

More than half (52.1%) of the subjects showed inappropriate behaviour towards stimulus response training by a speech therapist. In fact, the majority (67.1%) of the family members of the candidate did not commit to the home-based programme.

Medical and anatomical contraindications for cochlear implant surgery

Of the 73 candidates, 23 (31.5%) were found to have medical contraindications (Table III). Among them, 24.7% of the candidates had absolute medical contraindications in the form of severe global developmental delay (GDD). The causes of GDD were congenital brain or spinal malformation (63.6%), followed by genetic causes (27.3%) and brain infection (9.1%) (Table IV). A further 14 (19.2%) candidates had anatomical contraindications for cochlear implant surgery. As indicated in table IV, more than half the candidates had relative anatomical contraindications.

Candidates that fit all criteria except family factors

Among all the evaluation criteria, the family factor is the only one that is potentially modifiable. Unfortunately, 4 (7.1%) candidates were not selected for cochlear implantation solely due to failing to meet this criterion.

Determinants of cochlear implant selection outcome

Table V shows the bivariate and multivariate analysis of factors associated with the cochlear implant selection outcome. The bivariate analysis showed that hearing aid compliance, behaviour, medical contraindications and family commitment were significantly associated with cochlear implant evaluation outcome; however, the subsequent multivariate logistic regression revealed only family commitment as a significant predictor of implant candidacy evaluation outcome.

DISCUSSION

In this study, the 23.3% uptake rate of cochlear implantation by potentially suitable candidates aged less than 48 months old was considerably lower than in other countries. For example, in the United States of America[22], more than 50% of children with profound hearing loss receive at least one cochlear implant.

Published data have revealed that patients who were implanted before the age of 24 months were more likely to acquire age-appropriate spoken language. Nevertheless, in our study, the majority of children (53.4%) were only assessed for cochlear implant candidacy at an age older than 24 months. The candidates who underwent cochlear implantation were also anticipated to be older, and this could have an impact on their post-surgery speech outcomes. The mean age of children undergoing surgery was 40.1 months in Malaysia.[13] Children born with sensorineural hearing loss and implanted before the age of 42 months have shown age-appropriate latency responses within 6 months of cochlear implantation.[23]

Cochlear implants for children in Malaysia have been entirely supported by national funding. The candidacy criteria are therefore comparatively more restrictive than in other countries with purely self-financing models. Malaysia has a national policy in place that regulates the candidacy for implantation, and a multidisciplinary team decides whether an individual is a suitable candidate. The results of this study suggest that the only significant predictor of cochlear implant eligibility was the commitment of the family to the continuous auditory learning and assessment program offered by the otorhinolaryngology team. This was considered to be the most important component among all the criteria, most likely due to the degree of participation of the family in the pre-and post-operative stages that are critical in the process of recovery of the deaf child. A national survey of paediatric cochlear implant audiologists conducted by Kirkham identified parental factors (93%) as significant predictors of cochlear implant rehabilitation outcomes.[24] Holt et al. also found that the family environment affected the cochlear implantation outcomes of language development in prelingually deaf children between 0.7 and 6.8 years of age.[25]

Children with additional disabilities, such as cognitive disabilities, challenge the ability of the clinician to assess the possible value of a cochlear implant. The current literature indicates that the majority of children with multiple disabilities continue to make progress, although often at a slower pace than in children without additional disabilities. Children with additional disabilities and with motivated families should therefore be given the same opportunity to have access to hearing and to develop their communications skills as any other child with hearing difficulties.[26]

The 10-year report of the National Ministry of Health Cochlear Implant Program revealed that the only factor influencing the post-implant functional outcome was household income.[13] The social demographics of the family, such as the parents' level of education and the household income, were not explored in the present study. These factors may influence the family's commitment to clinical appointments.

Strengths

This is the first study to evaluate the association between the selection criteria for cochlear implants and the outcome of candidacy selection in Malaysia. Our study is also the first to assess the uptake rate of cochlear implants by potentially suitable candidates younger than 48 months of age in Malaysia.

Limitations

The sample size in this study was relatively small, as shown by the wide confidence interval in the statistical analysis. This research also only included those cochlear implant candidates who were assessed by the Cochlear Implant Satellite Hospital Committee in Perak, Malaysia. The generalisation of these results is therefore limited to local settings.

Implications for practice

These results demonstrate the need for education awareness programs to improve parents' understanding of the indications, significant benefits and reasonable risks of cochlear implantation for deaf children. In addition, family responsibilities, such as engagement in the planning and implementation of therapeutic interventions, should also be highlighted assiduously in counselling. This will also potentially improve the dedication of the family to the continuous auditory learning and assessment program offered by the clinical team. The reasons for poor family commitment should be explored; these are likely multi-

factorial and could include competing priorities for the child (e.g. the child was scheduled for multiple appointments), travel difficulties, family dynamics and household income. In the future, a qualitative study that takes into account the perspectives of the family may be useful for identifying the challenges and for learning together with the family about different ways of dealing with obstacles and difficulties in the course of cochlear implantation. A number of factors are related to failed cochlear implant candidate selection; however, the primary predictive factor is poor family commitment. This is a factor which can be changed, and future studies should probe the underlying reasons to allow other potential cochlear implant candidates to benefit from this technology.

CONCLUSION

Given the proven benefits of cochlear implantation in children, it is likely that not all children who are potential candidates will receive cochlear implants. The main predictive factor associated with the outcome of the candidacy selection was the degree of family participation in the assessment and speech and language training programme. A number of factors are related to the rejection of a candidate for a cochlear implant, but poor family commitment is the key predictive factor. This is a factor that can be changed, and future studies should look at the reasons for poor family commitment that prevents cochlear implant candidates from benefiting from this technology.

CONFLICT OF INTEREST

The research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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ETHICS

The study has been registered with the National Medical Research Register (NMRR-19-1673-48993) and obtained ethical approval from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

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