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Effectiveness of Cochlear Implant in Children with Profound Sensorineural Hearing Loss Below Poverty Line in Rural India: A Longitudinal Study

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Abstract: The *objective* of the study was to measure the effectiveness of the aided auditory threshold and speech-language performance of children with cochlear implant use longer than 4 years in North-East region of rural India. *Study design*- A longitudinal study of ninety-three children with mean age of 3.8 years with standard deviation (SD) of 0.9 years (61 males and 32 females) with unilateral cochlear implant below poverty line in rural India and with 2 years intervention of post implant auditory verbal therapy were included in the study. This study was based on the assessment of outcomes of unilateral Cochlear Implantation while reviewing various measuring scoring systems like Categories of Auditory perception (CAP), Milestones for early communication development, Receptive Expressive Emergent Language Skill (REELS), Auditory Skills Checklist (ASC); for articulation assessment- available articulation test in local language and spontaneous speech sample and Aided audiogram thresholds. The *results* on the average of the post operative auditory global threshold (T0) just after cochlear implantation was 33.53±8.91dBSPL and after continuously using 4 years cochlear implant for auditory global threshold was 32.56±6.43dBSPL. The ASC revealed 46% were able to comprehend, CAP findings shows there is a significant difference ($p=0.039$, at $p<0.05$ level) in the auditory skills based on duration of hearing aid use before implantation. The difference between hearing aid user and non-hearing aid user was significant ($p=0.034$, $p<0.05$). The differences in the performance of children with Digisonic SP implantees group and Nucleus freedom implantees group in terms of aided auditory threshold and speech-language performance were not significant. Cochlear implant with auditory verbal therapy under ADIP scheme is evidence based treatment for children with profound hearing loss for speech and language acquisition and best hearing performance. This increased access to mainstream education, greater opportunities for employment, societal and economic benefits. In conclusion cochlear implant was beneficial to children with profound hearing loss, contributing to hearing performance and speech-language acquisition. However, there were indications of challenges with certain aspects of language, specifically receptive vocabulary and expressive grammar, suggested requirement of longer period intervention of post implant auditory verbal therapy. The results obtained seem to remain stable over the years.

Keywords: Cochlear Implantation, Language Development, REELS Score, Auditory Verbal Habilitation

1. Introduction

The American Academy of Paediatrics Task Force on Newborn and Infant Hearing stated, "significant bilateral hearing loss has been shown to be present in approximately 1 to 3 per 1000 newborns in the well-baby nursery population, and in approximately 2 to 4 per 1000 infants in the intensive care unit population [7]. Cochlear implants are the vital medium of access to hearing for people with severe to profound sensori- neural hearing loss. Cochlear implant candidacy are given with the FDA approval and have changed substantially over period of time. By year 2000, FDA had approved and extended the implantable age down to 12 months. Under the ADIP (Scheme of Assistance to Disabled Persons for purchase / fitting of aids / appliances) Scheme, the Ministry of Social Justice and Empowerment, Government of India [8] provides free unilateral cochlear implant to children with severe to profound hearing loss less than 5 years of age (prelingual hearing loss) with family income less than 15000/- per month. The cochlear implant facilitates improved auditory perception of speech and environmental sounds along with improved expressive language skills. However, Several factors that have been identified as predictors of post-operative performance, such as duration of hearing impairment, age of onset of hearing impairment, and age of implantation, the process of the auditory rehabilitation, the family participants in the therapeutic process and preoperative residual hearing level, failures and deterioration of CI, later disease of the central or peripheral auditory pathways, all may influence the final performance [5, 12]. However, it is still not known if these factors also have influence on the long term auditory and speech-language performance results, nor if these benefits are stable in the long-run.

Aims: This study aimed to measure the effectiveness of the aided hearing threshold and speech-language performance of rural children with usage of cochlear implant for more than 4 years.

2. Methods

The participants included 93 rural children with profound sensorineural hearing loss, pre-lingual deaf, family income less than 15000/- per month, underwent cochlear implantation under ADIP Scheme between the period January 2014 and December 2016. Sixty three children with Digisonic SP cochlear implantees and 30 children with Nucleus freedom cochlear implantees and who had cochlear implantation done for more than four years were selected. 3 years was the warranty period of speech processor of CI provided by the companies, hence 1 year more than warranty period had been consider.

Children were selected for CI based on behavioural observation audiometry, Impedance audiometry, OAE as an initial screening test. Brainstem evoked response audiometry which together revealed bilateral profound sensorineural hearing loss; and reflected benefits from the use of hearing aids for a period of 6 months, with medical and psychological contraindications, and with realistic expectation of hearing and speech-language performance by the family.

The study design was longitudinal study from 1 month to 48 months post implantation. The children attended speech-language therapy for 3 sessions of 45 minutes of each in a week for 2 years at AYJNISHD, RC, Kolkata. The evaluation results were obtained just after cochlear implantation as baseline measure (within one month of cochlear implantation), and after 48 months continuous usage of cochlear implant.

The tools used for assessing auditory perception included aided audiogram threshold through free field audiometry, Receptive Expressive Emergent Language Skill [4] was used to measure speech-language acquisition and for articulation assessment the available articulation test in local language and spontaneous speech sample was used. Revised Categories of Auditory perception (CAP) developed by Archbold, Lutman and Marshall [2], is an index consisting of eight performance categories arranged in order of increasing difficulty, and Auditory Skills Checklist (ASC) developed by Meinzen-Derr, Wiley, Creighton, and Choo [10], It is a clinical tool for monitoring functional auditory skill development in young children with cochlear implants.

All data were entered in a database table of SPSS version 17.0 for the statistical analysis. The analysis were performed using parametric statistical methods such as t-student test to compare the average of two paired sample and Kruskal-Wallis test to compare the average of more than two independent samples.

3. Results

A total of 93 children underwent cochlear implantation in the period between January 2014 and December 2016 was included in the study. The average age of implantation was 3.8±0.9 years, with a minimum of 1.7 years old and a maximum of 5.4 years old. The majority of male children were 65.6% and female were 34.4%. No bilateral implants were performed. Right ear implantees were 81.7% and left ear implantees 18.3%. The duration of the deafness before the implantation was variable. The mean duration of deafness before the implant was 3.89±0.8, all children were pre-lingual hearing impaired. Digisonic SP Cochlear Implant model implanted with 67.7% (63/93) children (m=44, f=19) and freedom Nucleas model implanted with 32.3% (30/93) children (m=17, f=13). 70% of the implantees were attending regular school and 30% were attending special school. 72.5% of the implantees had used hearing aid for more than 6 months before implant.

Several causes of deafness shown in Table 1; the majority of the cases (40.8%) were idiopathic. Among the consanguineous marriage were the most frequently recognized, corresponding causes for about 35.5% of the children.

Table 1. *Several causes of deafness.*

Causes of deafness	percentage
Rubella/Mums/ Measles of mother	0%
Accident of mother	0%
Unsuccessful attempt of abortion	0%
Marriage within relative (consanguineous)	35.5%
Delayed birth cry	7.5%
Low birth weight	9.7%
High fever	3.2%
Meningitis	0%
Pathological Jaundice	3.2%
Unknown (idiopathic)	40.8%

The average follow-up period, which implicitly corresponds to the time of implantation, was 3.08 years±1.73, with a minimum period of 6 months and a maximum period of 6 years.

Few complications were identified with the one of the children who suffered head injury and subsequent damage to the CI; five children had an irreparable damage of the CI; and three children had an extrusion of the electrode beam, 8 children changed their speech processor.

The average of the post-operative auditory global threshold T0 (4 frequency. 5, 1, 2, 4KHz average audiometric threshold of the timing 0 after the cochlear implantation) was of 33.53±8.91 dB SPL. At T1 (4 frequency audiometric threshold after using continous 4 years CI), the average auditory threshold was 32.56±6.43 dB SPL.

Post operative audiometric threshold T0 and T1 in dBSPL at various audiometric frequencies such as 250Hz T0 35.53±10.47, T1 35.22±9.13; 500Hz T0 33.31±8.52, T1 32.73±7.66; 1000Hz T0 33.43±7.66, T1 33.04±7.31; 2000Hz T0 32.16±7.99, T1 30.26±7.21; 4000Hz T0 35.23±7.78, T1 34.33±6.57. When the various frequencies were compared between assessments T0 and T1, no statistically significant differences were found ($p > 0.05$), except for the frequency of 2 kHz ($p=0.08$, $p >0.05$).

The speech reception threshold (SRT) was 38.34±7.62 dB SPL after using 4 years continuous cochlear implant; however SRT could not done just after cochlear implantation due to insufficient words vocabulary.

Statistically significant differences were found in pure-tone audiometry, concerning the variables: age of implantation, for the frequencies from 1 kHz ($p=0.027$) and 2 kHz ($p=0.004$); time of hearing loss (congenital) at 2 kHz ($p=0.02$)); deafness aetiology (unknown), to 2 kHz ($p=0.027$)); and change of processor to 2 kHz ($p=0.009$)). However, there were no statistically significant differences between both assessment moments T0 and T1 for all of the other factors considered in pure-tone audiometry.

The results on Auditory Skills Checklist (ASC) after continuous use of 4 years implants revealed 100% of the implantees can detect sounds, 78% of the implantees could discriminate sounds, 72% of the implantees were able to identify sounds, and 56% were able to comprehend.

The CAP score used as one of the mean of evaluating the auditory benefit and language development 4 years post implantation. The results improved from 0 to average category of 5, where "0" sore of pre implantation and "5" score after 4 years implantation. Six implantees achieving category 8 and 9 in CAP were using hearing aid for more than 2 years before implant which shows there is a significant difference ($p=0.035$, at $p<0.05$ level) in the auditory skills based on duration of hearing aid use before implantation.

The result on "milestone for early communication development" showed semantics and pragmatics age 30 months. The results of Receptive Expressive Emergent Language Skill (REELS) showed 87.5% children had averaged receptive language age 36.2 months and expressive language age was 33.4 months post 4 years cochlear implantation, during which 2 years of continuous auditory verbal therapy was taken. 43.3% (41/93) implantees achieved receptive and expressive language of above 3 years were using hearing aid for more than 2 years before implant and this shows there is a significant ($p=0.023$, at $p<0.05$ level) in the speech and language skills based on duration of hearing aid use before implantation. Results of REELS also shows that there is a significant improvement difference ($p=0.007$, at $p<0.05$ level) in speech and language skills between male and female. Females' children improve better than males children in terms of speech and language acquisition skill.

Implantees achieving category 3 and 4 in CAP even after 4 years of implantation were not regular during therapy sessions. To find out relation between frequency of post implant auditory verbal therapy, and auditory behaviour and speech-language development "t" test was done and this showed that there is a significant improvement in auditory behaviour and speech-language development difference ($p=0.009$ at $p<0.05$ level) on frequency of post implant therapy session attended.

The available articulations test in local language and spontaneous speech sample were used to assess articulation skill and could be assessed 78.5% of the cases, for other cases Speech was not enough to assess In most of the cases misarticulated speech sounds were /s/ /sh/ /ch/ /chs/ /k/ /g/ /gh/ /th/ /bh //ph/ /r/ and /dz/ in the form of substitution, omission and distortion.

When compared to children with Digisonic implanted and children with Nucleaus freedom implanted group finding showed no significant difference in auditory global threshold in just after cochlear implant (T0) and after 4 years implantation (T1). Percentage of children with Digisonic SP implantatees showed better performance in CAP, ASC and REELS compared to Nucleus freedom implantees group. This may be due to large number of children implanted Digisonic SP compared to Nucleous freedom cochlear implant.

4. Discussion

The objectives of the study were to obtain the tonal benefits as well as the acquisition and development of oral language and its recognition, in children with CI. During post implant and post implant within the usage period of 4 years, the data demonstrate the ability of children with cochlear implants to develop speech-language performance and aided auditory threshold without deleterious long-term effects. With early CI in children between 1-5 years of age, marked improvements were observedin the domains of auditory perception and language acquisition. The results suggest that children implanted early in life demonstrate better development of speech, language and auditory skills. The results also suggest that if cochlear implantation is done at an earlier age, it will facilitate a series of developmental processes occurring during the critical period of initial language acquisition [5, 13].

The results are in consonance with the previous results reported by Peixoto, et al [11] studied to evaluate the effectiveness, according to the hearing threshold and language performance, of cochlear implants through a period of 10 or more years of follow-up. They found no statistically significant differences between early and late assessments, in paediatric cochlear implants users, after a 10 years period of cochlear implantation. Both speech and pure-tone audiometry seem to stabilize except for 2000 Hz where the results were even better after 10 years. Factors such as age at time of implantation, duration of deafness, aetiology and exchange of the speech processor do not seem to have a role in auditory performance after a long rehabilitation period. Verbal discrimination rates of words and phrases recognition were of 84.6% and 65.1%, respectively.

Beadle et al. [3] used the CAP as a means of evaluating the auditory benefit and language development for 5 and 10 years after implantation. The results improved from 0, at pre-implantation, to an average category of 6, at age 5, and 7, at 10 years old.

However, the detection and discrimination of sound do not guarantee that the child will be able to process the auditory information flow leading to an understandable language. Hence, it is reasonable to assume that the perception and speech comprehension is a key ingredient for the development of oral language. Therefore, the recognition tests for words and sentences are extremely important and are the most frequently used tests to evaluate the auditory benefits after cochlear implantation [6, 11].

Wie, von Koss Torkildsen, Schauber, Busch and Litovsky [15] reported that first 4 years after implantation, the language performance of children with cochlear implants became increasingly similar to that of their normal hearing peers. However, between 4 to 6 years there were indications of challenges with certain aspects of language, specifically receptive vocabulary and expressive grammar. Hence, there is a need for comprehensive longitudinal studies of the language development of children with cochlear implant beyond 4 years after implantation.

Over the years, several variables which contribute to the auditory and speech-language benefit obtained from the cochlear implant were defined according to short-term results. The factors which seem to be important for a good performance are the age at implantation, the pre-implantation average period of hearing aid uses the option for an audio-oral communication [9].

Albu, and Babighian [1] had reported a statistically relevant negative correlation between the duration of deafness and the final auditory performance. However, the current study showed that the effect of the predictive factors, such as age of implantation, duration and aetiology of deafness, on the auditory and speech-language performance seems to be diluted on the long term.

Qiu et al [14] reported that treatment with unilateral CI is a cost-effective hearing solution for children with severe to profound sensor-neural hearing loss in rural China. This increased access to mainstream education, greater opportunities for employment, societal and economic benefits.

Almost all children with cochlear implants whose speech intelligibility, speech perception, spoken language, academic and social development are far below that of children with normal hearing. There remains enormous variation in outcomes between individuals with cochlear implants. Other influences related to neural maturation and development, and also to complex interactions between demographic variables, environmental factors, intervention and learning processes, are not yet understood. A challenge for the future will be to make progress in understanding of these factors and processes in order to improve outcomes for a greater population of children with cochlear implants. Further follow-up of children with cochlear implants is required because cochlear implant is an electro-medical device susceptible to damage, as well as the fact that the auditory pathway itself can change in the long term.

The results of the study will help to determine a protocol to increase the success rate of cochlear implantation in India as well as in identifying the factors which could be responsible for reducing the success rate of the programme. It will help in better intervention programme for children with cochlear implantation by solving the affecting factors.

5. Conclusion

The CI confers a very important asset in treatment of congenital hearing loss. The results obtained seem to remain stable in the long-term and evidence showed that cochlear Implants in children offer real advantages in hearing, speech-language acquisition, educational, and communication abilities that can be expected to result in improved quality of life and employability without deleterious longterm effects.

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