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One-year experience with the Cochlear™ Paediatric Implanted Recipient Observational Study (Cochlear P-IROS) in New Delhi, India

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Abstract

Background: Currently, there is a significant lack of data concerning long-term outcomes following paediatric cochlear implantation in terms of quality of life. There is a need for a long-term, prospective study in this regard. This study aims at highlighting the preliminary results, one year post surgery of a five year prospective study.
Methods: The Cochlear™ Paediatric Implanted Recipient Observational Study (P-IROS) is a prospective, patient outcomes registry for routinely implanted children. The study collects data using questionnaires post-surgery and at regular intervals up to five years.
Results: At our Centre, 159 cochlear implant surgery procedures were carried out between January 2014 and December 2014. Category of Auditory Performance II score increased from '0' to '3' at six months and to '5' at 12 months for children aged 0–3 years, although this was not statistically significant. However, the same trend was statistically significant for the age 3–6 year and age 6–10 year brackets. The quality of life of the child improved significantly. Analysis of communication mode revealed a statistically significant overall shift to the auditory-oral mode from total communication.
Conclusion: Cochlear implantation is a life-changing intervention. The evidence in support of what it can achieve safely is clear. However, the costs associated with it raise the question if it will remain an effective option for life in all children. The Cochlear P-IROS is an attempt to answer the same over a five year period. Our study in New Delhi, so far concludes that cochlear implantation in a population with limited access to funds is very effective, one year after surgery.

Keywords: Cochlear implant surgery; Hearing loss; Cochlear implant outcome; Category of Auditory Performance; Quality of life

1. Introduction

Hearing loss affects about 5.3% (approximately 360 million) of the world's population (World Health Organization, 2012). Out of these, 9% are children. Severe to profound hearing loss is defined as hearing loss of 61 dBHL or more in the better ear (Mathers et al., 2000). Its incidence is estimated to be 4.8% in children aged 0–1 years and 6.4% in children aged 1–4 years (Sanderson et al., 2014). Prevalence and severity of hearing loss vary with some factors including socioeconomic status, exposure to infections, and consanguinity (Stevens et al., 2013). Lower income and increasing age lead to increased incidence of hearing loss (Stevens et al., 2013).

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The gold standard intervention for permanent severe to profound hearing loss is cochlear implantation. Candidates include children born with the permanent bilateral sensorineural hearing loss (Balkany et al., 2001, 2002). The impairment may range from moderate in the low frequencies sloping towards severe to profound in the higher frequencies. Apart from cochlear implantation, in the mild to moderate category of deafness, other options are also very effective, such as air conduction hearing aids, bone conduction hearing aids and middle ear implants. Children with absent cochlea and cochlear nerve can be candidates for brain stem implant. Research over the last few decades has revealed cochlear implant surgery to be a safe option for children and adults, with a major complication rate of 1.6% for children implanted bilaterally under the age of 18 years (Broomfield et al., 2013).

Despite advances in medical technology, clinics around the world have individualized clinical practices based on clinician training and expertise, published literature, and practices unique to that area. The available data to support uniform evidence-based practice is still very low. The National Institute for Health and Care Excellence (NICE) in the UK reviewed the body of evidence of cochlear implants and although recommended provision of bilateral simultaneous cochlear implant surgery for children born deaf, acknowledged lack of evidence in the field (Bond et al., 2009). Similarly, the National UK Audit of Paediatric cochlear implantation between 2010 and 2012 revealed strongly positive evidence in favor of the same (Cullington et al., 2013). However, the study did not measure the quality of life or other humanistic measures including education placement and literacy.

There seemed the need for a standardized electronic patient registry for the collection of data of cochlear implant recipients (Raz, 2005; Berrettini et al., 2011a) even though it was proposed that the same may be very costly (Berrettini et al., 2011b).

In an attempt to generate consistent collated and reported data set for cochlear implant recipients, the Cochlear™ Paediatric Implanted Recipient Observational study (Cochlear™ P-IROS) was developed by Cochlear™. This global, prospective, observational study, facilitates a unified approach for the assessment of patients worldwide in a structured format. The Cochlear P-IROS study design is based on the primary hypothesis of intra-subject improvement in auditory performance of children using implantable hearing devices across the world.

The objectives of the Cochlear P-IROS study are:

1. To evaluate the longitudinal improvements in auditory performance with implantable hearing aid devices in children using standardized questionnaires.
2. To provide statistically significant data to support patient management decisions at the clinical, regulatory, payer and policy level.
3. To compare the patient related or humanistic benefits such as educational placement, quality of life and patient satisfaction resulting from use of hearing implants in unilateral, bilateral and bimodal configurations.

This study has been conducted in an Indian private hospital setting, where funding for children from a lower socioeconomic demographic group was provided by a philanthropic foundation.

2. Material and methods

This study is part of the Cochlear P-IROS (Cochlear™ Paediatric Implanted Recipient Observational Study), a prospective, longitudinal, observational, international, multi center, patient outcomes registry for routinely implanted children. The study collects data using standardized and generic questionnaires at regular intervals up to five years through a secure web interface. The Cochlear P-IROS protocol and evaluation forms used have been described in detail previously (Sanderson et al., 2014). To date, clinics from Belarus, China, Cuba, India, Indonesia, Taiwan and Turkey have joined this study apart from our clinic.

Data were collected on patient comorbidities, device use, auditory performance, and quality of life, across different types of implantable hearing devices from a range of manufacturers. Patients were evaluated with a set of questionnaires prior to initial device activation (baseline) and at six monthly follow-up intervals up to 24 months and then annually thereafter.

The specific inclusion and exclusion criteria of the study are as follows:

Inclusion criteria:

1. Newly implanted prelingual and perilingual patients less than age 10 years, prior to the first time the hearing implant system is activated by the fitting of the sound processor.
2. Unilateral, bilateral or bimodal users of cochlear implants, electroacoustic devices, bone conduction implants, or other implantable hearing systems.
3. Parent/caregiver and/or patient are cognitively able to respond to self-administered/proxy assessment scales and willing to participate and sign the Patient Consent Form.

Exclusion criteria:

1. Patients with previous implant experience. This includes all brands and types of cochlear, bone conduction, electroacoustic and auditory brain stem implant systems.

2.1. Study period

The current study describes the outcomes six months and 12 months after surgery. It is planned that these patients will be followed up until five years from surgery.

2.2. Ethical and consent considerations

This study was evaluated and received ethical approval by the Columbia Asia Hospitals (Palamvihar, Gurgaon, and

Bangalore, Karnataka, India) Ethical Committee. All patients/parents signed a written consent form after the patient was implanted to ensure the decision to participate in the registry remains independent of the type and brand of the device implanted.

2.3. Questionnaires used for evaluation included

Evaluation forms for the clinician:

Clinician baseline form
Clinician follow-up form
The Categories of Auditory Performance – II (CAP-II)
Unaided hearing threshold form
Aided hearing threshold form
End of study form

Evaluation forms for the parent/caregiver:

Implant recipient baseline/follow-up forms
Children using hearing implants Quality of Life (CuHI–QoL)

The primary outcome measure was the CAP-II, a standardized measure of the perceived functional hearing of the child, from the clinician's perspective (Gilmour, 2010). The CuHI–QoL was used as the secondary outcomes measure, to evaluate the perceived quality of life of the child, expectations for the child, and the impact/burden on the family, from the parent-proxy perspective (Sanderson et al., 2014). This evaluation form was developed in collaboration with academics and clinical experts in the hearing implant industry (Sanderson et al., 2014). Validation of the CuHI–QoL is underway in Australia (Sanderson et al., 2014).

Following forms were recommended as optional by Cochlear P-IROS protocol (Sanderson et al., 2014) and not used in this study:

Health Utilities Index – Mark III (HUI 3)
Speech spatial and qualities of hearing scale (SSQ)
SSQ – Parents version

2.4. Study hypothesis

a. Post Implant performance for all patients on the Categories of Auditory Performance–II (CAP–II) are superior to pre-implant performance (baseline) and show incremental improvement at each subsequent post-implant assessment points (6, 12, 18, 24 months and annually up to 5 years) during the study.
b. Post implant assessment of quality of life for the patient and family via the CUHI–QoL questionnaire as assessed by the parent or caregiver are superior to quality of life assessed at baseline (pre-implant) and show incremental improvement at each subsequent post-implant evaluation time point (6, 12, 18, 24 months and annually thereafter for up to 5 years) during the study.
c. Patients who enter mainstream school during the study enter at an age-appropriate time.
d. The proportion of patients who are participating in mainstream school with no additional support is higher than the proportion of patients in other categories of school placement.

2.5. Study implementation

The baseline forms were completed after surgery, before discharge from hospital or prior to first switch-on of the sound processor. The follow-up questionnaires were completed in the clinic at the time of follow-up visits, coordinated by a patient coordinator who is well versed in the study. A clinician and other approved clinic staff entered the data into the Cochlear P-IROS web-based platform online after the patient/caregiver had completed the questionnaires given to them in their local language in print. No identifiable personal data were collected in any of the forms or preserved in the database. An automated query system built into the Cochlear P-IROS web platform ensured high data quality and integrity.

2.6. Statistical analysis

Categorical variables were summarized using percentages while continuous data were summarized using means and standard deviations (SDs). Significance at the 0.05 level was examined using Pearson's chi-square for education placement and Spearman rho, for parent/clinician satisfaction. The primary endpoint (CAP-II over time) was analyzed using an ordinal mixed-effects model including time, and age at implantation as fixed effects, and the participant as a random effect. The results of this model showed the odds of being in a higher category compared with the current category over time, at any given timepoint. Age at implantation was adjusted for, since it has been shown to be significantly associated with outcome (Bond et al., 2009). Summary subscales of the CuHI–QoL (Child's QoL, Impact on Family, and Parent Expectations) were analyzed using linear mixed-effects models also adjusting for age at implantation. Given the percentage of missing data was small (<10%) for the majority of variables, missing data were not imputed. Statistical analyses were performed using the RStudio Version 0.98.1074 (Windows).

3. Results

At our Centre, 159 cochlear implant surgery procedures were carried out by the first author between January 2014 and

December 2014. This cohort included 112 recipients of Cochlear CI24RE (ST) with CP802 sound processor; 42 recipients of the Advanced Bionics 1J with Harmony sound processor; and five recipients of the Digisonic SP cochlear implant and sound processor. Of 159 patients, 150 were implanted at less than age 120 months and constituted the paediatric population. These patients were enrolled and analyzed in the P–IROS platform.

A rate of follow-up at 90% was achieved at six months. At the time of analysis, the primary measure, the CAP-II was completed for 146 children at baseline, 135 children at six months, and 48 children at 12 months. The latter figure was low due to staggered nature of patient recruitment, i.e., at time of analysis, 12-month follow-up was not due for majority of the patients.

The main source of referral to this practice were Audiologists (73%) and parents of other children (12%) who had been operated in our centre (Fig. 1). Other sources of referral for paediatric patients included ENT surgeons (9%), General Practitioners (GP's) (3%), Speech Therapists (1%), and others (1%).

The mean age at implantation was 4.95 years (54.9 months) with a standard deviation of 1.89 years (22.7 months). The minimum age of implantation was 15 months. 25 children were operated at ages 0–3 years, 81 children at 3–6 years and 44 children at 6–10 years. The etiology of deafness was unknown in the majority of patients (Fig. 2).

Analysis of the socio–economic profile of these patients revealed both fathers and mothers to be largely educated up to secondary school (48% and 49%, respectively). Most of the fathers were employed in mid-level non-professional jobs (85%), and almost all mothers were housewives (92%). Around 45% and 46% of the patients belonged to the 'middle-income' (<8000 USD per annum) and 'low-income' (<5000 USD per annum) brackets, respectively.

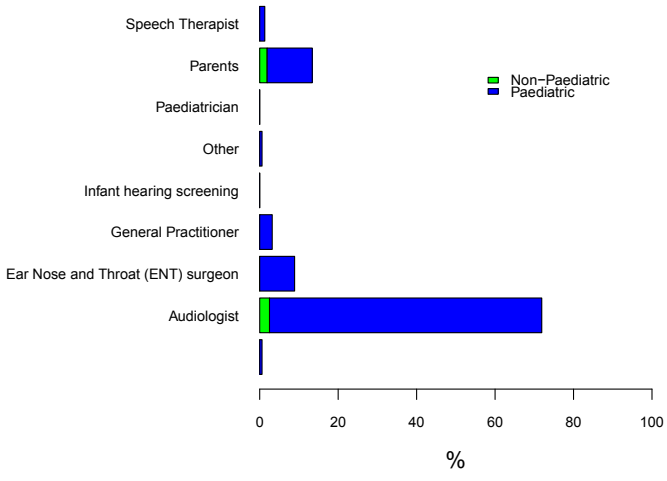

Fig. 1. Sources of referral for paediatric and non-paediatric patients.

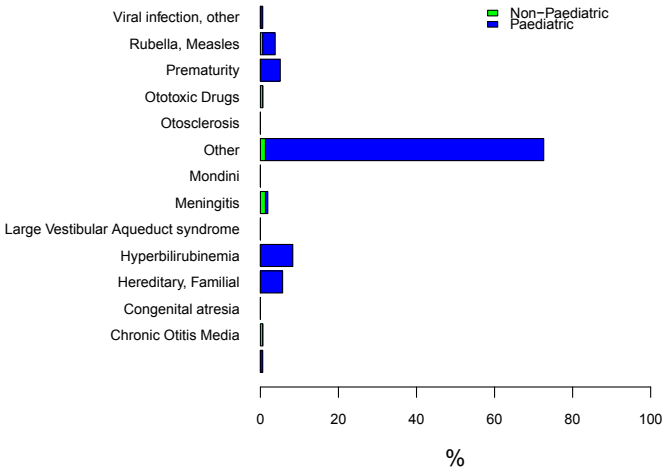

Fig. 2. Etiology of deafness for paediatric and non-paediatric patients.

For recipients' aged 0–3 years, the CAP-II score increased from '0' to '3' at six months and '5' at 12-month follow-up, although this was not statistically significant (Fig. 3). However, the same trend was statistically significant ($p < 0.05$) for the age 3–6 year and age 6–10 year groups (Fig. 3). These CAP-II scores are defined as;

- '0', No awareness of environmental sound or voice.
- '3', Identification of environmental sounds.
- '5', Understanding of common phrases without lip reading

Quality of life of the child, measured by the CuHI–QoL scale improved significantly ($p < 0.05$) for the cohort as a whole. So did the impact on family ($p < 0.05$). Parent expectations realistically dropped after the first three months (Fig. 4).

Analysis of communication mode changes revealed a statistically significant ($p < 0.001$) overall shift to auditory-oral mode from total communication, defined as 'a combination of visual cues, audition, and cued speech' in all age groups (Fig. A1).

For children who had not yet entered school in the age 3–6 year group, one can see the shift from staying at home to a preschool intervention where possible, at baseline (Fig. A2). Also evident was the greater frequency towards mainstream integration in the age 6–10 year group (Fig. A2).

For the paediatric cohort, parent versus clinician satisfaction at six month follow-up were largely aligned on most fronts, including hearing, listening, language development, and overall progress (Rho: 0.62, 0.63, 0.55, and 0.21, respectively; $p < 0.001$). A similar trend was also observed at 12-month follow-up (Spearman's Rho: 0.55, 0.39, 0.55, and 0.36, respectively; $p < 0.001$).

No patients have dropped out of the study yet. Overall the primary hypothesis predicting a significant improvement in CAP-II score stands proven from this study. However, long term 2–5 year outcome using the same platform will bring out the final fate of children operated at this centre.

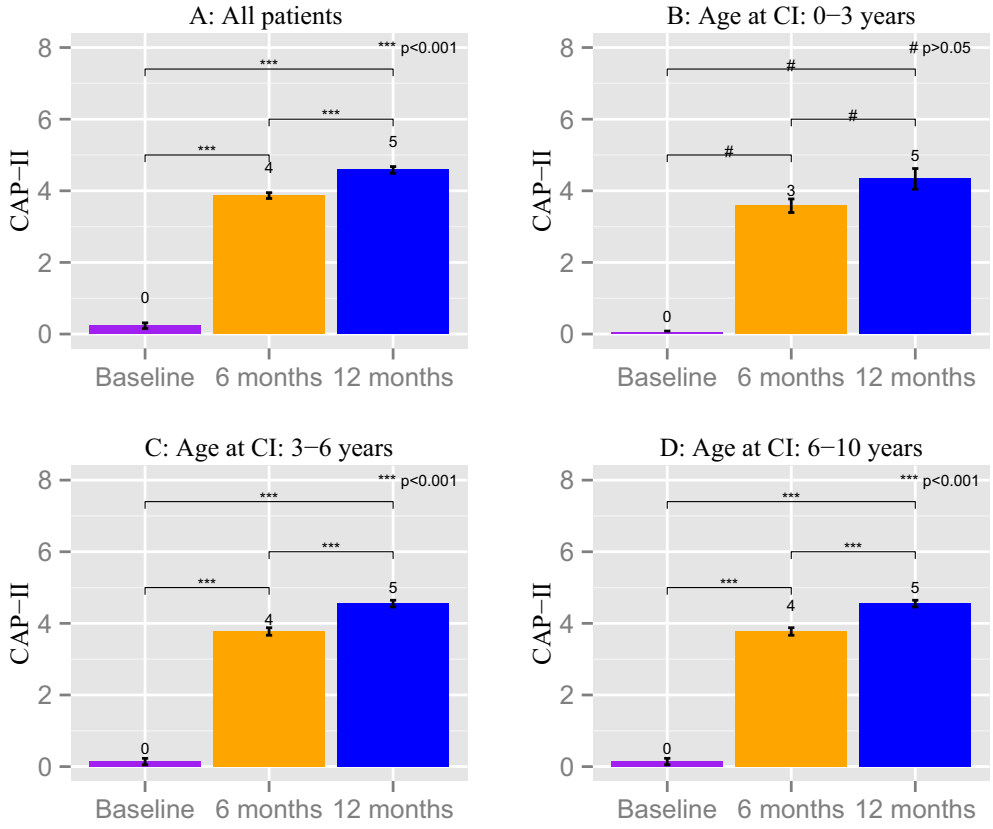

Fig. 3. The performance in the CAP-II for all paediatric CI recipients, and by age at implantation. Abbreviations: CAP, categories of performance; CI, cochlear implant. Notes: The figure highlights the mean and median (shown in numbers) CAP-II performance of CI recipients, from baseline to six and 12-month follow-up. In Panel A, the performance of all children who received a CI at age <10 years is shown; whereas in Panels B–D, the performance of different age sub-groups are illustrated. These CAP-II scores are defined as; • '0', No awareness of environmental sound or voice. • '3', Identification of environmental sounds. • '4', Discrimination of speech sounds without lip reading. • '5', Understanding of common phrases without lip reading.

4. Discussion

The Cochlear P-IROS has supported a unique collection of outcomes data from a large cohort of children using cochlear implants. At the six month and 12 month follow-up intervals, children have made significant progress in their auditory performance. Our current results are a snapshot of the outcomes noted at one year from the start of the study in an Indian private hospital setting.

Analysis of the source of referral of these patients revealed a unique referral pattern probably typical of a developing country in the Indian subcontinent. A huge majority of these children were referred by Audiologists. The next largest category were parents of other patients. ENT surgeons and GPs referred the least number of patients and Paediatricians seemed to not refer at all. Most of these patients have access primarily to private care with philanthropic funding support. State screening for hearing loss is patchy and not effective. When parents note that their child is typically not speaking any words around the age of two, they take him or her to the local audiologist who then refers to a Cochlear Implant Program. Paediatricians do not refer directly to a Cochlear Implant Program. It is possible that they refer these children to the local audiologists who then take the lead in these childrens' treatment. It is also possible that the Paediatricians and most GPs are not looking out for hearing loss. Another reason may be that they are not very well networked to ENT surgeons and fulfill their responsibility by handing the case to an Audiologist. Contrary to previous anecdotal information, this fact is a stark new one. It is probably more important to direct activities related to increasing awareness and creating interest about Cochlear Implants through Audiologists than Paediatricians or GPs as is the case currently in India.

The maximum number of children, who were implanted in this program were in the age range of 3–6 years. The next highest frequency was in the age 6–8 year range, and least of all were in the ideal age of implantation of less than age 3 years. This could be because of delay in diagnosis, but it could also be due to nonavailability of funding options. Universal Neonatal screening for hearing loss is adopted by most new hospitals in India, however in the vast majority of

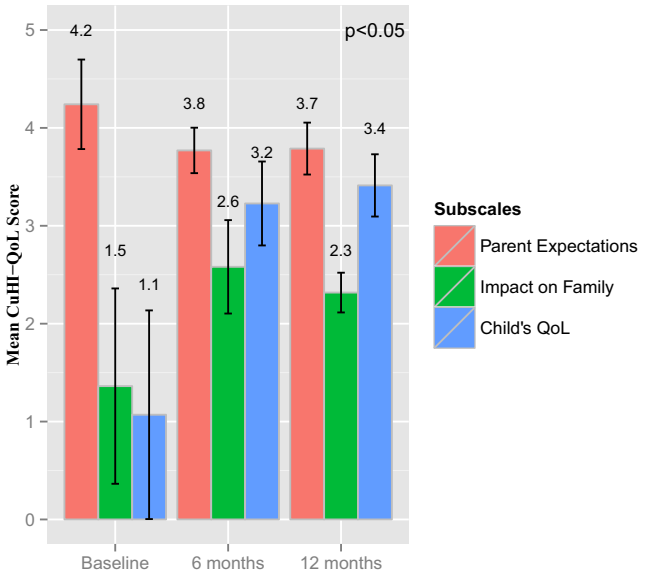

Fig. 4. The performance in the CuHI−QoL scale for all paediatric CI recipients. Abbreviations: CuHI−QoL, Children using Hearing Implants Quality of Life; CI, cochlear implant; QoL, quality of life. Notes: The figure shows the mean performance in the CuHI−QoL for all paediatric CI recipients, across time. Significant differences ($p < 0.05$) were observed in 'Parent expectations', 'Impact/burden on family', and 'Child's QoL' sub-scales, when compared with baseline, at six month and 12-month follow-up intervals.

births in this country, screening for hearing loss does not figure as standard practice. As such parents suspect hearing loss only when the child is expected to speak and does not, such as at age two years. It is difficult for the parent to make the decision in favor of Cochlear Implant surgery in good time. They take time to decide and arrange for funds since the same is not provided by state (other than few exceptional ones) or covered by insurance and the price of treatment even with a low-cost device is well beyond what they can afford. Non-involvement of Paediatricians and GPs in the referral process further adds to the delay.

The etiology of hearing loss could not be established in most cases. Within our study setup, the investigation of etiology of disease did not compulsorily include Genetic testing due to extra costs involved there. Viral infections, prematurity and history revealing an inherited pattern were the most common etiologies observed in this cohort (Fig. 2).

Education of fathers and mothers was mostly at secondary school level. While most mothers were housewives only, fathers were in all kinds of low to medium level skilled jobs with almost none in high paying professional roles like Lawyers and Doctors. This was the case since almost all patients enrolled in this program were funded by an external philanthropist and, therefore, the program sub-selected those patients who needed financial support. The annual income of the vast majority of these patients was less than 8000 USD.

4.1. Category of Auditory Performance-II (CAP-II) score

The CAP-II score increased from '0' at baseline to '3' at six months, and '5' at 12 months, in the age 0–3 years group (Fig. 3). However, these trends were not statistically significant in this group. The reason for this most likely is not in the poor performance of this group but instead in the small numbers of children in this age group. We say this because of the trends noted in the other age groups as described next. In the age 3–6 years and age 6–10 years groups, the score improved from '0' at baseline to '4' at six months and '5' at one year. These trends were strongly statistically significant ($p < 0.001$). As expected, with uncomplicated surgery and good early rehabilitation, these patients are performing at levels expected of them. Surprisingly this trend is also seen in those implanted after the age of six. It may be that this group will plateau off in their performance earlier than the younger groups in future assessments.

4.2. Quality of life

The CuHI−QoL questionnaire evaluating parent expectations revealed a statistically significant shift to reduced expectations after six and 12 months (Fig. 4). This was expected as initial expectations at the time of surgery are replaced by more realistic ones as the parents gather more information about how the device works and the importance of rehabilitation in due course. The impact on family increased from baseline to six months as the need to maintain and manage the cochlear implant speech processor was added to their responsibilities as well as the time and resources that now needed to be spent on taking the child for mapping and rehabilitation regularly. This change was statistically significant for the group (Fig. 4).

The child's quality of life improved significantly from baseline to six months and 12 months as captured by the questionnaire (Fig. 4). Access to even environmental sounds adds significantly to the child's happiness. Receptive language development to even CAP score of '4' to '5' added hugely to the child's ability to bond with the immediate family. This resulted in a sea-change in behavior and confidence of the child. The same child who was frustrated and screaming all the time was now much more calm and collected and interested in all our review meetings. This was so even if his receptive and expressive language skills were still far from reaching their optimum levels. The questionnaire captured this aspect of the child's development very well.

There were large variations in the CuHI- QOL scores that indicated variability in parent/caregiver perceptions of the family's expectations for the child, the potential impact/burden, and child's quality of life, especially at baseline (Fig. 4). These variations in the scores tended to drop by the 12-month follow up, once outcomes were more measureable for these families.

4.3. Communication mode

Analysis of communication mode at baseline, six, and 12-month intervals revealed a statistically significant shift from total communication to auditory-oral mode for all age-at- implantaton groups (Fig. A1). The change to auditory–oral mode was more marked in the age <3 years group. One could not compare the relative difference with the 12-month timepoint since the overall number of children who reached 12 months after surgery was small at this point in time. The overall statistically significant move in the right direction indicates that cochlear implantation is a very successful intervention for children age from one to eight years. At 12-month follow-up, they are still improving in their learning of receptive and expressive hearing, speech and language.

4.4. Mainstream schooling

In the age <3 years age group, there was no statistically significant move to education outside home although there was a visible trend (Fig. A2). This is understandable given the young age of the children and also the relatively small number of children in this group. In the age 3–6 years group, a statistically significant number of children not yet in school, moved from home to schooling options such as preschool, nursery and child care (Fig. A2). Cochlear implantation clearly empowered them and their families with the confidence that they will be functional and safe outside of home. In the age 6–10 years age group, the trend towards shifting to mainstream schooling and other outside home options is visible but the same was not statistically significant (Fig. A2). This may be owing to some limitation in this age group to adapt to the outside home environment. Whether they can overcome this in due course of time with rehabilitation and training would be interesting to note in further follow-up of this study. Whether time and training can make up for the loss of neural plasticity in this age group will get answered in 1.5–3 years follow-up.

4.5. Parent vs clinician satisfaction

The study investigated if parent and clinicians satisfaction with recipient's progress were aligned at six months and 12 months after surgery. At six months, there was a moderate but statistically significant correlation between parent and clinician satisfaction in hearing progress, listening progress and language development and limited but significant correlation in overall progress. In the age 0–3 years group, there was a significant alignment in hearing progress only. In the age 3–6 years group, there was a significant alignment in all domains. In the age 6–10 years group, there was significant alignment in hearing, listening, and language only but not in overall progress.

At 12-month follow-up there was a significant alignment of parent and clinician satisfaction in hearing progress, listening progress, language development but not in overall progress. For age 0–3 years group there was no significant alignment in parent and clinicians satisfaction at 12-month follow-up. In the age 3–6 years group, there was significant alignment in listening progress only. In the age 6–10 years group, parent and clinician satisfaction was well aligned and statistically significant in hearing, language and overall progress. At younger ages, parents' expectations did not match with that of the clinicians satisfaction. However the same was better aligned in the older age groups. The relatively smaller number of children that were followed-up to 12 months may also be affecting the trends reflected in this study at current stage.

5. Conclusion

Cochlear implantation is a life-changing intervention. This has been established beyond doubt. The evidence in support of what it can achieve safely in terms of developing receptive and expressive speech and language is clear. However, the crucial need for auditory verbal training and mapping, the need to maintain an external and internal bionic device, the costs associated with paying for initial treatment and later maintaining it for life, raise the question if it will remain an effective option for life, for all who receive it. The P-IROS is an attempt to answer the same over a five year period in various populations, worldwide.

Our study in New Delhi, India, so far concludes that cochlear implantation in a population with limited access to funds is very effective, one year after surgery. It will be very interesting to see the performance of this cohort of patients five years later.

Acknowledgement

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Appendix.

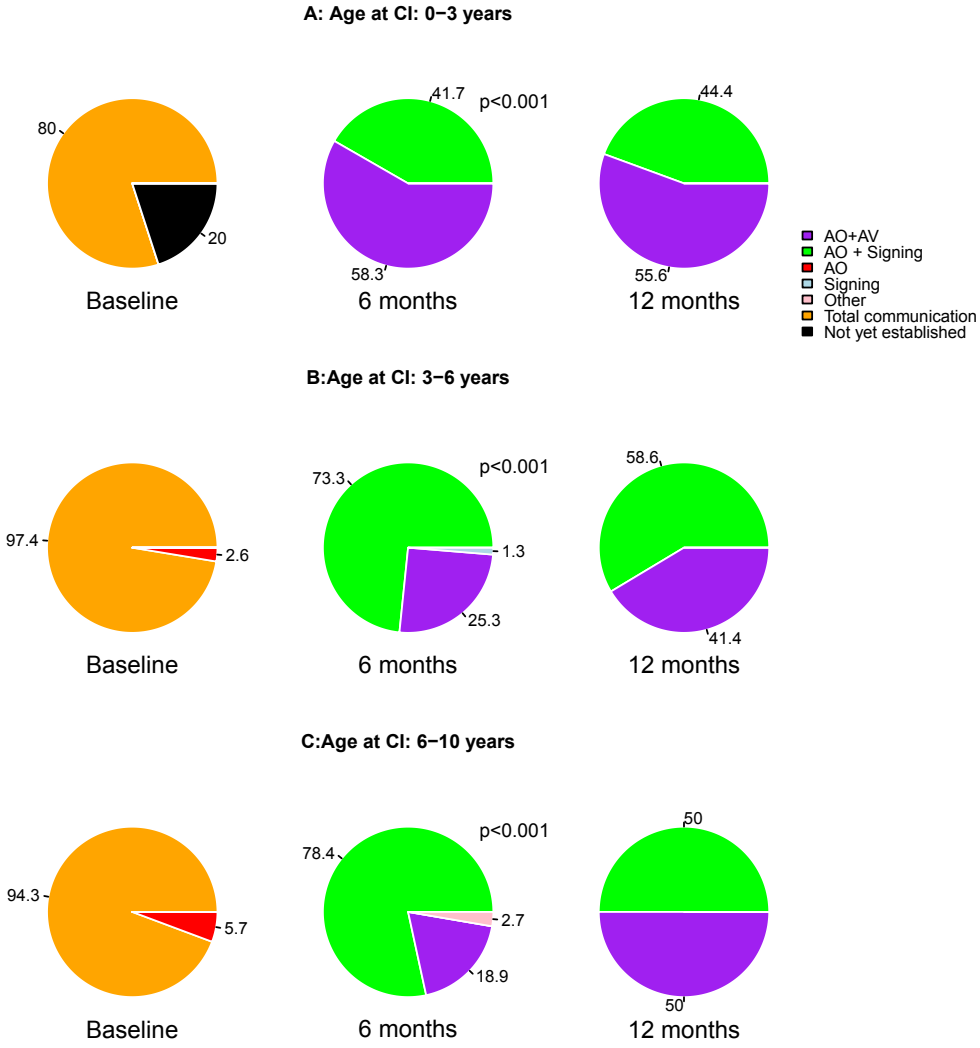

Fig. A1. The shift in communication mode for paediatric CI recipients by age at implantation. Abbreviations: AO, auditory oral; AV, auditory verbal; CI, cochlear implant. Notes: The figure illustrates the shift in mode of communication for three age-at-implantation groups, across time. There were significant changes in mode of communication of children from baseline to six months and 12 months, across all age groups examined ($p < 0.001$). At baseline, the majority of children had 'Total Communication', defined as a combination of visual cues, audition, and cued speech.

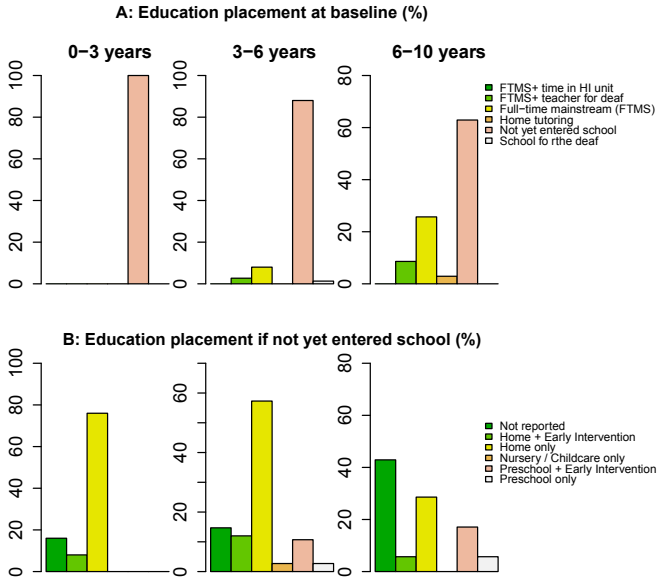

Fig. A2. Education placement of paediatric CI recipients at baseline, by age at implantation. Abbreviations: CI, cochlear implant; FTMS, full-time mainstream, HI, hearing impaired. Notes: The figure shows the educational status of paediatric CI recipients at baseline, by age at implantation. The analysis of educational placement at six and 12-month follow-up was limited by the incompleteness of the data. However, it is rare to observe a dramatic change in the education status over a period of 12 months.

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