Audit of Bilateral Simultaneous Cochlear Implantation in Pediatric Population: South Indian Study

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Original Investigation

Abstract

Objective: To conduct a medical audit of bilateral simultaneous cochlear implantation (CI) in patients with severe prelingual sensorineural hearing loss (SNHL).

Methods: A medical audit of a tertiary care ear, nose, and throat center in Southern India was conducted on data collected from January 2007 to December 2014. All cochlear implantees <6 years of age with severe bilateral SNHL who underwent bilateral simultaneous CI were included in the present study. The exclusion criteria were children >6 years, sequential bilateral CI, revision cases, abnormal or malformed cochlea, and children with global developmental delay in milestones. Subjective outcome scores used were Category of Auditory Performance (CAP) and Speech Intelligibility Rating (SIR).

Results: The CAP and SIR results showed that 20% of implantees achieved peak scores of 7 and 5, respectively. Mean CAP and SIR scores at 12 months were 5.4 and 3.1, respectively.

Conclusion: The present study supports the claim that bilateral CI in severe prelingual bilateral SNHL is better than unilateral and recommends that bilateral CI should be the standard of care in children.

Keywords: Medical audit, bilateral hearing loss, cochlear implantation, auditory perception, speech intelligibility

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Cite this article as: *Kumari A, Goyal S, Chauhan N, T S, R KC, Kameswaran M. Audit of Bilateral Simultaneous Cochlear Implantation in Pediatric Population: South Indian Study. Turk Arch Otorhinolaryngol 2018; 56: 36-41.*

This study was presented at the 3rd Annual Conference of IAOHNS, Aug 25-28, 2016, Kolkatta, India.

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Received Date: 02.10.2017
Accepted Date: 02.01.2018

DOI: 10.5152/tao.2018.2804

Introduction

Deafness is one of the major disabilities that adversely affect the development of speech and cognitive abilities in children. Unilateral cochlear implantation (CI) is the accepted treatment for children with severe bilateral sensorineural hearing loss (SNHL) in providing auditory perception and speech development. However, benefits are limited in noisy environments such as classrooms or playgrounds. This limits the learning abilities, acquisition of language and knowledge, and development of social skills.

Various studies support the fact that speech discrimination, directionality or sound localization, hearing in noise, and speech are better with binaural implantation (1-4). Although the benefits of bilateral CI are debatable, it is gradually finding its own niche in developed countries worldwide (National Institute on Deafness and Other Communication Disorders, 2011). However, it is still uncommon in developing countries, mostly because of financial constraints and complications. Medical audits to assess the outcomes of bilateral simultaneous CI in children is lacking in developing countries such as ours. However, such medical audits from various centers across our country can serve in the future as both national and international reference scales of comparison.

The aim of the present study is to conduct a medical audit of subjective outcomes of bilateral simultaneous CI in children with severe bilateral congenital SNHL which would serve as a reference scale for future studies. The objectives include: 1) to record subjective outcome measures available at our center of all bilateral

simultaneous CIs, 2) to record complications requiring cochlear reimplantation, and 3) to compare subjective outcomes with unilateral CI.

Methods

A medical audit of a tertiary care ear, nose, and throat research and referral center in Southern India was conducted from January 2007 to December 2014. Informed consent was obtained from all the patients and the approval of the Institutional research ethics board was also obtained. Data were collected from our medical records department.

All children with severe bilateral SNHL who underwent bilateral simultaneous CI were included in the audit. The inclusion criteria comprised children <6 years of age. The exclusion criteria were children >6 years, sequential bilateral CI, revision cases, abnormal or malformed cochlea, and children with global developmental delay (delayed motor and communication milestones with lower intellectual function) to reduce bias in outcome measurements. All our implantees underwent CI using United States Food and Drug Administration approved cochlear implants.

Category of Auditory Performance (CAP) and Speech Intelligibility Rating (SIR) were used to record the subjective outcomes in implanted children at our center. CAP is a hierarchical scale of auditory perceptive ability ranging from 0 (i.e., no awareness of environmental sounds) to 7 (i.e., can use the telephone with a familiar talker). It is a measure of supraliminal performance denoting auditory performance in daily life (5, 6). On the other hand, SIR is used to qualitatively quantify speech intelligibility in day-to-day real-life situations. It consists of five performance categories ranging from "pre recognizable words in spoken language" to "connected speech is intelligible to all listeners" (7).

The secondary objective is to study the complications requiring cochlear reimplantation in bilateral CI and compare with available literature. However, measures such as sound localization, speech recognition in quiet and background noise, parental perception, and quality of life were not included in the audit as these data were not recorded at our center and hence not available.

Third, to compare the subjective outcome of bilateral simultaneous CI with unilateral CI at our center, appropriate age- and sex-matched unilateral CIs performed at our center during the study period were included. The exclusion criteria were unilateral cochlear implantees with abnormal or malformed cochlea and implantees with global developmental and revision cases to reduce bias in outcome measurements. In patients with severe congenital bilateral to profound hearing loss undergoing unilateral CI, the choice of ear for surgery at our center is decided based on anatomy, hearing levels of both ears, and the handedness of the patient. The ear with normal anatomy is given preference over the ear with abnormal radiologically detected inner ear or cochleovestibular nerve anatomy. In case the inner ear anatomy is normal in both ears, the ear with a slightly better hearing is given preference. If both the ears are equally worse with normal inner ear anatomy, then the individual is implanted on the side of his handedness as this would make the handling of the cochlear implant by the child easier.

Age and sex-matched bilateral CIs were compared with unilateral CI with respect to their subjective outcomes (CAP score and SIR rating) using Mann-Whitney U test (non parametric tests because of small sample size and non parametric data) and Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Corp.; Armonk, NY, USA).

Results

The total number of patients who underwent CI at our institution during the study period was 632 out of which only 28 patients (4.43% of total CI) had bilateral (sequential or simultaneous) CI. At our center, CI is performed under two broad categories: 1) Tamil Nadu Chief Minister Health Insurance Scheme, under which unilateral CIs were done for all children under 6 years of age and 2) private patients. All private patients are appropriately counseled and explained about the difference between unilateral and bilateral cochlear implants with emphasis on benefits and cost involved, unless it is not indicated because of anatomical anomalies. All 28 patients who underwent bilateral cochlear implants were private patients who could afford the cost of two implants.

Among the 28 bilateral CIs, only six had sequential CI and the remaining 22 had simultaneous CI. Of the 22 bilateral simultaneous CI, 18 patients were <6 years of age and the remaining 4 were >6 years of age and were excluded from the audit. Of the 18 patients, three had a history of global developmental delay (delayed motor and communication milestones with lower intellectual function) and were again excluded from data collected to reduce bias. Thus, we had data of 15 patients with bilateral simultaneous CI available for audit. The male:female ratio was 8:7. The mean age at CI was 2.27 years with 12 implantees (80%) <3 years of age and three implantees (20%) between 3 and 6 years of age. All 15 patients had normal inner ear and cochleovestibular nerve anatomies.

The mean CAP scores were 3, 4, and 5.53 at 3, 6, and 12 months, respectively. The mean SIR ratings were 1.67, 2.00, and 3.13 at 3, 6, and 12 months, respectively. Results of CAP score showed that 20% (3 out of 15) of implantees achieved a score of category 7 (use of telephone with known listener) and 46.6% (7 out of 15) achieved a score of category 6 (understanding of conversation without lip reading) or more at 12 months. This was also evident with SIR with 20% (3 out of 15) achieving a score of 5 (connected speech is intelligible to all listeners and child is understood easily in everyday con-

texts) and 53.3% (8 out of 15) of children achieving a score of 4 (connected speech is intelligible to a listener who has little experience of a deaf person's speech) or more at 12 months of implant age. Details are as shown in Table 1.

Overall, there were two cases (2 ears out of the 30 ears, 6.67%) that required cochlear reimplantation, both having unilateral hard failure of the device, one after 3 years and the other after 10 years. Among the unilateral implantees (604 ears during the study period), a total of 22 ears (3.64%) had revision CI surgery. The most common cause was device failure (59.1%) followed by surgical site infection, middle ear infection, and electrode array malposition and extrusion. The other causes for cochlear reimplantation such as surgical site infection, electrode array extrusion or malposition, and middle ear disease were not present among the bilateral implantees. Details are shown in Table 2.

Age- and sex-matched bilateral CIs were compared with unilateral CI with respect to their subjective outcomes (CAP and SIR) as shown in Table 3. In view of small sample size and nonparametric data, Mann-Whitney U test was performed for

Table 1. List of patients implanted with bilateral CI. Subjective outcomes of the bilateral simultaneous cochlear implantees at 3, 6, and 12 months and mean scores

		Subjective outcome scores					
		Category of auditory perception			Speech intelligibility rating		
Patient serial number	Age at CI in years/sex	3 months	6 months	12 months	3 months	6 months	12 months
1	1.3/M	3	4	5	2	2	4
2	2/F	3	4	6	1	1	2
3	6/M	4	6	7	3	4	5
4	4/F	2	3	5	1	1	1
5	1.17/M	1	2	4	1	1	1
6	1.41/M	2	3	5	1	1	2
7	2.5/M	2	3	6	1	3	5
8	1/M	3	4	5	2	2	4
9	3.41/M	3	3	5	1	1	2
10	1.75/M	4	5	6	2	3	4
11	1.25/F	2	4	5	1	1	2
12	3/F	4	4	6	1	1	4
13	2.66/F	4	5	7	2	3	4
14	1.33/F	2	3	4	1	1	2
15	1.25/F	6	7	7	5	5	5
Mean	2.27	3	4	5.53	1.67	2.00	3.13

CAP: category of auditory performance; CI: cochlear implantation; SIR: speech intelligibility rating

Table 2. Etiology of cochlear implant failures and reimplantation among cochlear implantee at our center

	Etiology							
	Device failure		Surgical site infection	Electrode array extrusion	Electrode array malposition	Middle ear disease		Total
	Hard failure	Soft failure				Active squamous COM	Infection	
Unilateral CI (n=604 ears)	11	2	4	1	2	1	1	22 (3.64%)
Bilateral simultaneous CI (n=30 ears)	2	0	0	0	0	0	0	2 (6.67%)
Total	13	2	4	1	2	1	1	24

CI: cochlear implantation; COM: chronic otitis media

Table 3. Comparison of outcome of bilateral simultaneous cochlear implantation versus unilateral cochlear implantation

	Categroy of auditory perception (CAP) mean score			Speech intelligibility rating (SIR) mean score		
Subjective outcome measures	**3 months**	**6 months**	**12 months**	**3 months**	**6 months**	**12 months**
Bilateral CI	3	4	5.53	1.67	2.00	3.13
Unilateral CI	2.06	3	4.73	1.20	1.73	2.73
Mann-Whitney U test: p	0.041	0.05	0.04	0.31	0.84	0.49

CAP: category of auditory performance; CI: cochlear implantation; SIR: speech intelligibility rating

statistical significance between the two groups. It was found that although there was a statistically significant difference in the auditory perception (better in bilateral CI), there was no statistically significant difference between the two groups in terms of speech intelligibility.

Discussion

Unilateral CI has successfully provided significant improvement in auditory perception and speech intelligibility in children with severe bilateral SNHL. Substantial body of literature (1-4), including William House Cochlear Implant Study Group (CISG), acknowledges the benefits of bilateral CI and endorses it in clinically appropriate children (8). William House CISG states that use of two CIs substantially expands the receptive sound field, which is consistent with the psychoacoustic literature. A study has shown that with simultaneous bilateral CI, there is no interaural difference in latency between the two sides unlike sequential implants that result in potential disruption to bilateral brainstem processing based on timing cues (9).

In the present audit, we had a total of 15 bilateral simultaneous implantees with a male:female ratio of 8:7. A total of 80% of implantees were ≤3 years.

In the present audit of bilateral simultaneous CI, CAP score of 6 or more was achieved in 46.6% of implantees and an SIR score of 4 or more was achieved in 53.3% of implantees at 1 year of auditory verbal therapy post-implantation. Mean CAP score and SIR score at 12 months were 5.4 and 3.1, respectively, in the present study as shown in Table 1. The CAP test results of a medical audit performed at our center few years ago for children and adults with unilateral CI showed that 23% of implantees achieved a score of category 6 or more at 12 months of auditory verbal habilitation after implantation between 1-5 years of age (10). The study also observed in its audit that children in the age group of 1-5 years with unilateral CI achieved a peak CAP score of 7 in 10% and a peak SIR score of 5 in 13% at 12 months of auditory verbal therapy. In the present study on comparing age- and sex-matched bilateral simultaneous CIs with unilateral CIs with respect to subjective outcome score, a statistically significant better outcome in terms of auditory perception was obtained in the bilateral CI group. However, there was no statistically significant difference in terms of speech intelligibility outcomes.

Binaural mechanisms that use head shadow effect and central processing of cues based on timing, frequency, and level between ears markedly enhance speech understanding and sound localization compared with listening with only one ear, and it is clear that both children and adults perform better with two CIs than with one (8). Both peak CAP and SIR scores at 1 year are higher in the present study with bilateral simultaneous CI than in our previous medical audit of unilateral CI. We can establish two possible assumptions from the outcomes. First, bilateral implantees have better auditory perception and speech intelligibility than unilateral implantees. Second, and the more logical assumption, bilateral implantees achieve peak auditory perception and speech intelligibility faster than unilateral implantees. Only a long-term study (follow-up data of 5-10 years) will be able to decide if unilateral implantees are able to catch up with bilateral implantees in terms of outcomes.

The limitation of CAP and SIR is an ordinal, nonlinear scale (5-7). This implies that it cannot be assumed that change in performance from categories 1 to 3 is equivalent to that from categories 2 to 4. It is also unclear how much superior one category level is from another. Hence, consideration needs to be given to these factors while using CAP and SIR scoring. However, CAP and SIR scoring systems are practical and accepted standard scaling criteria for auditory performance and speech perception after CI in children (5-7); hence, it is in our center and in the present audit.

Children with bilateral implants have advantage of binaural summations. Binaural summation is defined as the sensation that a signal is perceptually louder when hearing with two ears compared with one ear. A meta-analysis by Schafer et al. (11) and others has shown that bilateral CI recipient has a better advantage in noise by improvement in speech recognition in noise compared with a unilateral CI recipient (12, 13). Many studies have reported marked improvements in head shadow effects and squelch effect when comparing single versus bilaterally implanted patients (13-15). There is also a significant improvement in quality of life in children implanted with bilateral CI as compared with unilateral CI (16). In the present

audit, we did not have data to assess the binaural summation benefit, parental perception, and quality of life measure.

The incidence of revision CI surgery from various studies around the world ranges from 4.1% to 18.5% with higher incidence in children than adult implantees (17-19).

The most common reason for cochlear reimplantation worldwide includes device failure (58%-78%) followed by medical causes (3%-37%) and electrode displacement (6%-16%) (17, 20, 21). The only indication of cochlear reimplantation in the present study was two cases of hard failure of device (6.67%) for bilateral CI as depicted in Table 3. This factor of need for cochlear reimplantation can be a huge financial burden for patients and needs to be explained to the family during counseling for bilateral CI.

Several studies and CISG have advocated for bilateral CI to be considered the standard of care treatment option for adults and children with bilateral advanced degree of SNHL (8, 22). Our audit performed in a developing country supports bilateral CI in children with severe bilateral SNHL. However, future studies with large number of patients and long-term follow-up data are required to give a conclusive statement.

Limitation of the study

Since the sample size was small, no statistical correlation was carried out. Since data for sound localization test, binaural summation and hearing in noise test, parental satisfaction, and quality of life measures were not available, they were not evaluated and studied.

Conclusion

The present audit supports the claim that bilateral CI in severe prelingual bilateral SNHL is better than unilateral CI, which is statistically significant for auditory perception, however, at increased cost. We also recommend that future studies should be performed to analyze the sound localization capability and hearing in noise test of bilateral implantees and compare it with unilateral implantees.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Madras ENT Research Foundation (MERF EC-AUG 16/16).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.K., A.K., S.G., N.C., T.S., K.C.; Design - M.K., A.K., S.G., N.C., T.S., K.C.,; Supervision - M.K., A.K., S.G., N.C., T.S., K.C.,; Materials - A.K., S.G.; Data Collection and/or Processing - A.K., S.G., K.C.R.; Analysis and/or Interpretation - A.K., S.G., N.C.; Literature Review - A.K., T.S.; Writing - S.G., A.K.; Critical Reviews - M.K.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

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