A Retrospective Study of Cochlear Re-Implantations - Experience from a Large Centre in India

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Original Investigation

Abstract

Objective: Cochlear re-implantation (CRI) is becoming increasingly common throughout the world. However, studies regarding CRI incidence and etiology are lacking from developing countries like ours. The aim of this study was to present the Indian experience with CRI based on our experience. Objectives were to determine the incidence and the indications of CRI and the cumulative survival rate (CSR) of cochlear implantation (CI).

Methods: Our study was a retrospective one, conducted at a tertiary care centre in southern India. 1,500 consecutive cochlear implanted ears from 1997 to 2016 were studied. All patients who underwent CRI during this period were included in the study.

Results: There were a total of 53 ears (31 male and 22 female ears) who underwent CRI. This gives an incidence of 3.53%. The most common indication of CRI was device failure in 39 ears contributing to 73.6% of the total CRI. The overall CSR of CI in pediatric population was 96.5% over a 20-year period.

Conclusion: The CRI incidence and etiology at our centre appears to reflect the findings of the literature. Cochlear implant centres across the world should report the CSR of devices used at their respective centres so that it can be made an important criterion in choice of implant.

Keywords: Cochlear implantation, device failure, cumulative survival rate, developing countries

Introduction

Cochlear implantation (CI) in contemporary world is accepted as the standard of care for patients with severe cochlear hearing loss. With increasing number of CI being carried out at numerous centres across the world, more and more of these implantees (more so children) will require cochlear re-implantation (CRI) in their lifetime. Device failures (hard failure or soft failure), medical conditions (infection, acute or chronic otitis media, and implantation cholesteatoma) and electrode array extrusion or misplacement are frequent causes of CRI (1). Studies have shown that CRI is a safe surgery with maintenance of audiological performance (2, 3). However, studies regarding CRI are lacking from developing countries such as India.

Maurer et al. (4) in their study concluded that cochlear implant reliability data should be considered during the choice of implant for each individual. Since such data are lacking in literature across the world, including India, it becomes imperative that centres with a high number of cochlear implant surgery need to report the cumulative survival rate (CSR) of cochlear implants at their respective centres.

The aim of the study was to present the data of CRI and the reliability data of cochlear implants based on our experience. The objectives were to study the incidence and indications of cochlear re-implantation and determine CSR of cochlear implantation.

Methods

Our study was a retrospective one, conducted at a large cochlear implant centre in India. A total of 1500 consecutive cochlear implanted ears (bilateral implants were counted as two implanted ears)

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from 1997 to 2016 were studied. All patients who underwent CRI in this period were included in the study. All cases of revision cochlear implantation where cochlear explantation was not carried out were excluded from the study. The relevant data was retrieved from our medical records department. Informed consent was taken. Institutional research ethics board approval was obtained. Appropriate statistical analysis was performed, using Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Corp.; Armonk, NY, USA).

Results

In total there were 53 ears (3.53% of the 1500 consecutive implanted ears) who had undergone CRI at our centre. Out of the 53 ears, 31 CRI were male patients and remaining 22 were female patients. The mean age of primary implantation, failure and CRI was 4.7 years, 6.2 years and 6.3 years, respectively. The mean duration of implant usage before undergoing re-implantation was 1.6 years. All patients requiring CRI were less than 8 years of age, except one who was 28 years of age requiring CRI after 10 years because of hard failure of implanted device.

The most common indication of CRI was device failure in 39 ears (34 ears with hard failure and 5 ears with soft failure) contributing to 73.6% of the total re-implantation. The next common indication of CRI was medical causes (16.98%), which included surgical site infection (4 ears), chronic otitis media–active squamous disease (3 ears) as shown in Figure 1 and middle ear infection (2 ears). The other causes of CRI in our study included electrode array extrusion (3 ears) and electrode array malposition (3 ears, 2 in hypotympanum and 1 in Eustachian tube) as shown in Figure 2. One of the patients had both electrode array extrusion and chronic otitis media–active squamous disease as cause of re-implantation at the time of presentation. It was also noted that of the two patients with bilateral simultaneous cochlear implantation had undergone re-implantation because of hard failure (one after 10 years and the other after three years) while the contralateral implant was functional. The different etiology necessitating CRI are tabulated in Table 1. It would be interesting to note that there were total of 15 patients with surgical site infection (SSI), all of whom were hospitalized and initially managed with wound debridement, local flap

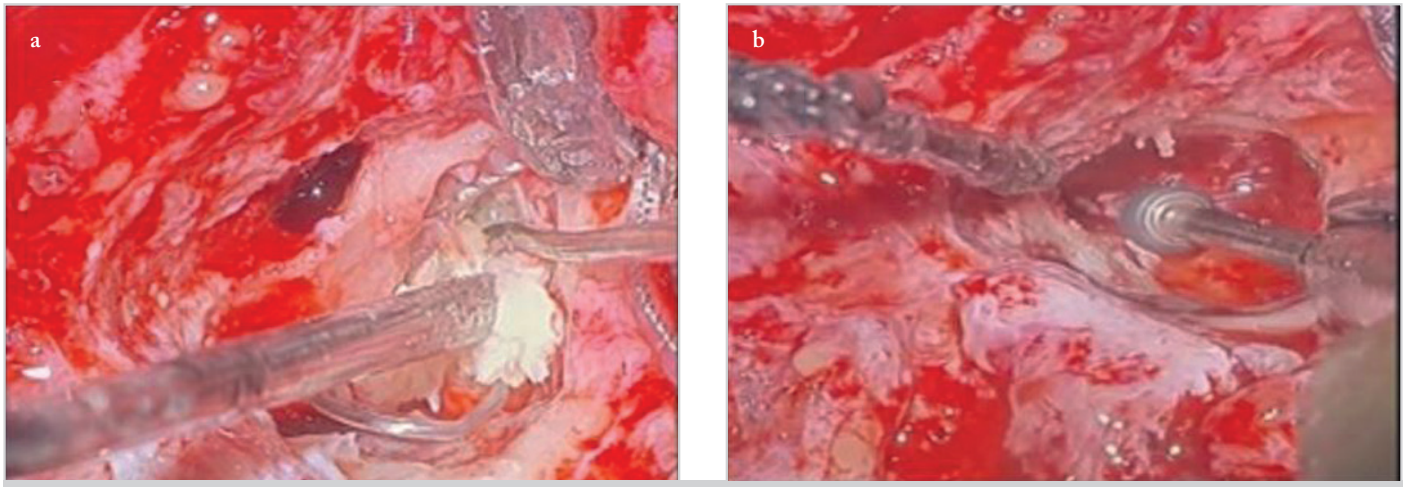

Figure 1. a, b. Case of cholesteatoma post cochlear implantation in left ear exposing cholesteatoma in mastoid cavity with electrode array and lead in situ (a). After taking care to meticulously remove internal implant device in toto, canal wall down mastoidectomy was performed with blind sac closure (b)

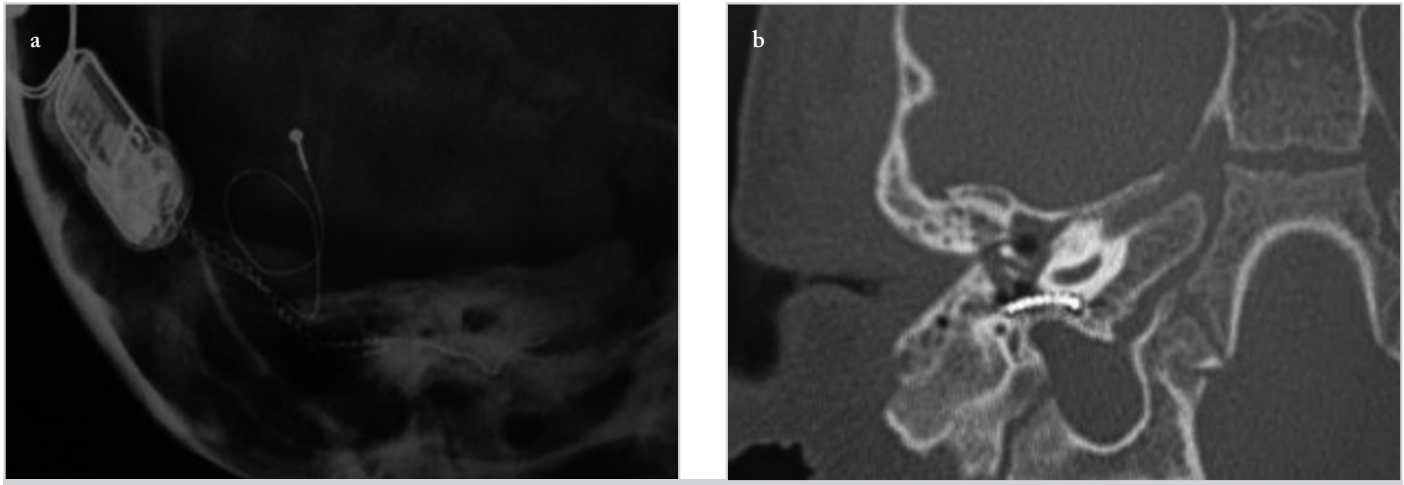

Figure 2. a, b. X-Ray of mastoid (right ear) showing the malpositioned array into the Eustachian tube (a). HRCT scan of temporal bone (axial section) of one of our patient showing the malpositioned electrode array in the hypotympanum. Revision surgery was performed and complete insertion of same electrode was achieved succesfully. Intra-operative impedance and ECAP measurments post re-implantation were satisfactory (b)

rotation and injectable antibiotics. Only four patients (26.67%) eventually required cochlear explantation and re-implantation because of SSI.

We further divided the cochlear implantation failure cases into two groups. Group A comprised of implantees in whom CRI was required within one year of primary implantation. While Group B comprised of implantees in whom CRI was required after one year of primary implantation.

There were total of 34 ears (64.15% of total CRI) in Group A as detailed in Table 1. The mean age in this group of patients was 4.2 years for primary implantation and 5 years for CRI. The mean duration of implant usage before undergoing re-implantation was 0.8 year (ranging from one month to 12 months). The most common indication for CRI in this group was device failure in 26 ears (22 ears with hard failure and four ears with soft failure) contributing to 76.5% of the total CRI. The other causes of CRI included SSI (four ears), electrode array extrusion (two ears) and electrode array malposition (two ears). None of the patients had chronic otitis media (active squamous disease) or middle ear infection as an etiology for CRI in this group.

The remaining 19 implanted ears (35.84% of total CRI) requiring CRI belonged to Group B as detailed in Table 1. The mean age of primary implantation and CRI in this group was 5.5 years and 8.5 years, respectively. The mean duration of implant usage before undergoing re-implantation was three years (ranging from 1.25 years to 10 years). The most common indication for CRI in this group was also device failure in 13 ears (12 ears with hard failure and one ear with soft failure) contributing to 68.4% of the total CRI. The other causes of CRI in this group was chronic otitis media – active squamous disease (three ears), middle ear infection (two ears), electrode array extrusion (one ear which coexisted with chronic otitis media – active squamous disease) and electrode array malposition (one ear).

Cumulative survival rate is the cumulative percentage of functioning implants over time and can be used to predict the reliability of the device within a given time frame. The overall CSR of cochlear implants in pediatric population was 96.5% over a period of 20 years at our centre.

Out of the total 1500 consecutive cochlear implantation included in the study, 419 implants belonged to Cochlear Limited (Australia) performed over 20 years (1997-2016). 10 of these implantees underwent CRI. This gives a CSR of 97.61% over 20 years. 56 implants were from Advanced Bionics (United States of America) performed between 2008 and 2016 (9 years period). Only one of these implants required CRI. This gives a

Table 1. Distribution of number of cochlear implantation (CI) failed based on time frame and etiological factor

	Number of implants failed based on time frame after cochlear implantation (CI) requiring re-implantation (CRI)				
	Group A	Group B			
Etiology	Less than 1 year after CI	Between 1-2 years after CI	Between 2-5 years after CI	More than 5 years after CI	Total
Hard failure	22	9	2	1	34
Soft failure	4	1	0	0	5
Cholesteatoma	0	1	1	0	2
Infection of middle ear	0	0	1	1	2
Cholesteatoma + Electrode array extrusion	0	1	0	0	1
Electrode array extrusion	2	0	0	0	2
Surgical site infection	4	0	0	0	4
Electrode array malposition	2	1	0	0	3
Total	34	13	4	2	53
Percentage of total	64.15	24.53	7.55	3.77	
Cumulative percentage	64.15	88.68	96.23	100	

Table 2. Failure rates and cumulative survival rate (CSR) from 1997-2016 of the three USFDA approved cochlear implants from a large cochlear implantation centre in south India

	Cochlear Ltd	Advance Bionic	Med El	Grand total
Period	1997-2016	2008-2016	2007-2016	1997-2016
Duration	20 years	9 years	10 years	20 years
Cumulative Total no of implants	419	56	1025	1500
Number of revisions	10	1	42	53
Failure rate	2.39%	1.79%	4.1%	3.53%
Cumulative survival rate (CSR)	97.6%	98.2%	95.9%	96.5%

CSR of 98.21% over 9 years. The remaining 1025 implants were from MED EL (Austria) performed over 10 years (2007-2016). Forty two of these patients underwent CRI. This gives a CSR of 95.9% over 10 years. The details of number of implants used over the years with the failures and CSR for each of the three United States Food and Drug Administration (USFDA) approved companies is given in Table 2.

Discussion

With increasing number of CI being performed throughout the world including developing countries like ours, most of these implantees, especially the pediatric population, will require CRI. Although several articles have been published on CRI (2, 3), similar studies regarding incidence and etiology are lacking from developing countries like India.

The reported incidence of revision CI surgeries from various studies around the world range from 4.1% to 18.5% with a higher incidence in children compared to adult implantees (1, 5-9). The incidence of CRI in the present study was 3.53% over a period of 20 years. The marginally lower incidence in our study could be justified by the fact that only cases of CRI were included in the present study, and patients who underwent revision surgery without cochlear explantation (e.g. surgical site infection managed without explantation) were excluded. Secondly, the lower incidence can be explained by the fact that most of the implants done at our centre belonged to the newer version of the implants. This is supported by studies having observed that cochlear implant failure rates have been reduced with newer implants (1, 6). In the present study the mean duration of device usage before explantation was 1.6 years (ranging from one month to 10 years), similar to studies available in the literature (1, 5, 8). Thirdly, the lower rate could be because at our centre we follow a standard technique of creating a receiver stimulator bed with tie-down holes and use of sutures to fix the implant. Receiver stimulator recess bed creation with sutures to secure the implant has been shown to be associated with a lower incidence of revision cochlear implantation compared to subperiosteal tight pocket technique in literature (10).

Studies have shown that the most common indication for CRI across the world is device failure (58-78%) followed by medical causes (3-37%) and electrode displacement (6-16%) (1-3, 5-7, 11). The most common indication of CRI in the present study was device failure (73.6%) followed by medical causes (16.98%), similar to world literature. It was noted that device failure was the most common cause for CRI both as an early presentation (64.1%) and as a delayed presentation (76.5%). A recent study by Gardner et al. (9) reported device failure as the most common cause for long term complication of pediatric cochlear implantation. However, none of the cases of early CRI were due to medical causes, probably because medical causes (like chronic otitis media squamous and middle ear infection) have a silent period before they become symptomatic and progress to a stage requiring CRI.

Electrode array malpositioning, though a rare complication of CI, is important because of its serious consequences. It can lead to both injury to important adjacent neurovascular structures that are within millimetres from the cochlea (vestibular system, neural structures within the internal auditory canal, facial nerve, and major vessels) and poor audiological outcomes (12-14). Hence, confirmation of the position of the electrodes intraoperatively by electrophysiologic measures (electrical impedance and neural response telemetry) and/or imaging becomes essential. In contrast, the absence of a detectable intraoperative neural response telemetry threshold has been observed in some patients even with a functional device in the correct location (15). We, at our centre, routinely use intraoperative electrophysiological measures to confirm functional status of electrodes. Imaging is not done intraoperatively at our centre. Post-operative imaging (X-ray) is resorted to in patients with abnormal cochlear anatomy or in doubtful cases where we do not get satisfactory intraoperative neural response telemetry.

The two most common anatomic sites for malposition of electrode arrays are the superior semi-circular canal, followed by the vestibule; while, the most frequent error is inadvertent implantation of a hypotympanic air cell, which is more likely to occur if the round window niche is not clearly identified (10, 14). In our experience, we had three cases of electrode malposition, two in the hypotympanum and one in the Eustachian tube. This may occur even in experienced hands if there is fibrous or bony obliteration of the niche, and thereby reliance on other landmarks (i.e., oval window position and stapedial tendon) becomes essential and important (16).

In the present study we also calculated the cumulative survival rate (CSR) of the cochlear implants used at our centre. The CSR of the three USFDA approved cochlear implants was 97.61% for Cochlear Nucleus over 20 years, 98.21% for Advanced Bionics over 9 years and 95.9% for MED EL implants over 10 years. The overall CSR of cochlear implants was 96.5% over 20 years at our centre, similar to the available literature (4). In a study by Maurer et al. (4) on the reliability of cochlear implants in both adults and children, the CSR was 91.7% over a period of 11 years.

Conclusion

This study from a cochlear implant centre in India provides objective evidence of incidence and various etiology for CRI. The CRI incidence and etiology at our centre appears to reflect the findings of the broader literature. With increasing number of cochlear implantations worldwide, there is going to be an increase in the requirement of CRI. Knowledge about the various causes of CRI and the temporal relation of causes of CRI will help in early identification of the etiology and its management. It will also help in adequate counselling of the patients both before implantation and in the follow-up of the implanted patients. The study also provides the CSR of the three USFDA approved implants performed at our centre. The reliability data can be utilized as an important factor in choice of implant by both doctors and in turn patients.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Madras ENT Research Foundation (MERF/EC-AUG16/15).

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

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