ORIGINAL ARTICLE

Cochlear Implants and Its Complications: A Retrospective Study

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Abstract

Aims: Cochlear Implant (CI) surgery is an effective and feasible alternative to restore hearing in severe bilateral hearing loss.

Materials and methods: This retrospective study estimated the prevalence of complications associated with CI surgeries done from April 1994 to March 2016.

Results: About 1,236 surgeries were performed on 933 pediatric patients and 79 adults. The cause of the deafness was congenital (90.91%), idiopathic (8.30%), and meningitis (0.79%). No speech impairment was seen in eight (0.86%) children. There was a history of consanguinity in 60.02% of patients.

Bilateral profound hearing impairment was common in 99.41% of patients. The previous CI was reported at 29.46%. Delayed milestones (13.39%) in children, hypertension (14.29%), and diabetes mellitus (15.18%) in adult patients were noted.

Right, cochlear implantation (47.43%), left (31.42%) and bilateral implantation (21.15%) were done. There were 17 (1.68%) complications (major 08, minor, 09) in adults. Superficial wound infection occurred in four patients (median 28 days, range 3–358 days) after implantation resolved on treatment. There was no significant ($p > 0.05$) relationship between the presence of comorbidities and complications.

Conclusion: Cochlear Implant is a safe procedure and the complications are within the acceptable limits.

Clinical significance: The complication rate with cochlear implants is within an acceptable range. Infections remain the most common complication. The procedure is safe.

Keywords: Bilateral sensorineural hearing loss, Cochlear implantation, Complications.

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Introduction

Cochlear Implant (CI) surgery is an effective and feasible alternative to restore hearing in severe bilateral hearing loss that does not improve after using an individual sound amplification device (ISAD).[1]

It is estimated that there are over 150,000 CI surgeries done in the world. Since the introduction of this technique, many publications have reported complications occurring after CI and various classifications have been proposed. Cohen and Hoffman[2] was the first to describe the complications stemming from the multichannel CI surgery in a representative sample. Then the European consensus statement on cochlear implant failures and explantations in 2005, issued a tool for estimating the complication rates and the reason for device failures. Since then, more recent publications have distinguished between minor, and major complications and complications requiring cochlear reimplantation. Global complication rate following CI has decreased gradually (from 40 to 4%) as a result of improvement of surgical techniques with smaller incisions and the use of increasingly miniaturized and biocompatible implants.[2–4]

In this study, we assessed the complications that were noted with CI surgeries with an ear surgery training program in the past 22 years.

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Conflict of interest: None

Materials and Methods

Ethical Considerations

Data of surgeries done during April 1994–March 2016 (22 years) was collected, after obtaining the Institutional Ethics committee's approval.

Study Design

This was a retrospective description study conducted in a Tertiary Care Center with an ear training program in South India.

Objectives

This study aimed to analyze the frequency occurrence of complications associated with CI surgeries with the objective of analyzing the complications after implantation.

Patients with severe to profound hearing loss, unilateral/bilateral, who did not benefit from using ISAD were considered for CI. The outcome included improved hearing, any complications associated, and its correlation to hearing.

Data Collection

Two data collectors reviewed and collected the relevant data from the medical records (inpatient charts, outpatient and operation theatre records) using a preapproved proforma. Demographic details, and etiology of hearing loss as ascertained by the otorhinolaryngologist, as documented, were collected; details of preoperative evaluation included otomicroscopy, audiometric testing, vestibular function testing, auditory brain stem evoked response, and imaging methods, operative details included the date of surgery, nature of the surgical procedure, type of incision (traditional or minimal), whether complete or incomplete insertion of electrodes and the implant used were collected. Postoperative follow-up included medications used, length of the hospital stay, and follow-up details of complications for 5 years.

Outcome Measures

Surgical complications were classified as major and minor (Table 1). The temporal relation of such occurrence is grouped as: at the time of surgery or within 24 hours of surgery (perioperative), 24 hours-1 week after surgery (early postoperative), >1 week after surgery (late postoperative).[5]

Results

In 22 years 1,236 surgeries were performed. Any patient record with incomplete data or loss to follow-up was not included in the review. Figure 1 outlines the statistics of patient enrolment.

We included 933 pediatric patients (6 months to 18 years) and 79 adults who underwent a cochlear implant.

Among the pediatric patients, there were 500 males and 433 females. There are 100 (10.72%) patients were aged <2 years and 8 patients (0.86%) were aged 18 years (Table 2). Mean ± SD age was 8.96 years ± 3.36.

Out of 79 adults (18–78 years), 45 were males and 34 were females. There are 50 (63.29%) patients who were in the age group of 19–30 years (Table 2). Mean ± SD age of the patients was 32 years ± 3.81.

Out of 933 pediatric patients, 923 (98.93%) had hearing impairment since birth and associated with delayed speech. There were 9 patients (0.96%) who had hearing defect after birth with a duration ranging from 6 months to 6 years, of whom one developed hearing impairment following typhoid fever. One patient developed hearing loss when he was 12 years old (5 years duration). No speech impairment was seen in 8 (0.86%) children. One had altered speech of 6 years duration. There are 8 (0.86%) developed hearing impairment following meningitis.

Out of 79 adults, 21 (26.58%) had hard of hearing since birth and had associated delayed speech. Others had a gradual onset of decreased hearing time ranging between 6 months and 4 decades.

The cause of the deafness was congenital in 920 (90.91%), idiopathic in 84 (8.30%), and meningitis in 8 (0.79%).

Bilateral profound hearing impairment was a common finding in 1,006 (99.41%) patients. One pediatric patient had left-sided profound hearing loss. There are 5 (0.49%) adult patients had unilateral right-sided sensorineural hearing loss. Mondini's

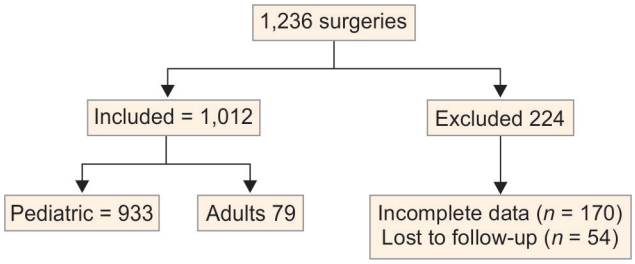

Fig. 1: Data collection and analysis

Table 2: Age distribution among the study population

Age group	*n (%)*
Pediatric	
<2 years	100 (10.72)
>2–<5 years	510 (54.66)
5–10 years	280 (30.01)
>10–16 years	35 (3.75)
>16–18 years	08 (0.86)
Adults	
19–30 years	50 (63.29)
30–60 years	20 (25.32)
>60 years	09 (11.39)

Table 1: Reported complications of CI

Major complication	*Minor complication*	*Nonsurgical complication*
Meningitis	Vertigo/dizziness	Allergic reactions
Flap necrosis	Tinnitus	Facial stimulation
Improper electrode placement	Labyrinthitis	Device failure
Permanent chorda tympani syndrome	Ear drum perforation	Pre-existing ear conditions
Permanent facial nerve paresis	Vestibular neuritis	Abnormal ear anatomy
Cholesteatoma	Ear canal fenestration	Middle ear/cochlear fibrosis
Transient chorda tympani syndrome	Incision infection	

Table 3: Past illness/conditions in the study population

Past illness	*n (%)*
Left cochlear implant	12 (10.71)
Left cochlear implant and h/o discharge from the right year – 2 years ago	03 (02.68)
2 episodes of typhoid fever – 1 years ago	01 (0.89)
Right cochlear implant	08 (07.14)
Rt cochlear implant and loss of hearing following an episode of fever	02 (1.79)
H/o meningitis – 1–4 years ago	08 (07.14)
H/o using hearing aid	09 (8.04)
Right cochlear implantation and explantation	04 (03.57)
H/o hydrocephalus, VP shunt (rt–3 years ago), GTCS–2years, on medication	01 (0.89)
Delayed cry by 5 mins after birth, Low APGAR score, H/o seizure on second day after birth	05 (04.46)
Snoring, mouth breathing 6 months	01 (0.89)
High grade fever, surgery @ age 6	01 (0.89)
Methemoglobinemia	05 (04.46)
Delayed milestones	15 (13.39)
B/L cochlear implantation – 5 years ago	04 (0)
Known case of bronchial asthma	05 (04.46)
Known Down's syndrome + Cong heart disease; Post VSD closure with mild residual pulmonary hypertension	01 (0.89)
Right stapedectomy – 10 years ago	02 (1.79)
H/o road traffic accident April 2016 postoperative status: Frontal craniotomy endonasal repair + Extradural repair CSF rhinorrhea	01 (0.89)
H/o fever – 9 years ago	01(0.89)
Bilateral Acoustic schwannoma	04 (03.57)
H/o loss of vision at 4 years of age	01 (0.89)
TB abdomen – 13 years ago, DM	01 (0.89)
Ch otitis media, rt ear surgery in 2018	01 (0.89)
Hypertension	16 (14.29)
Diabetes	17 (15.18)
Total	129

$n = 1,012$; $n = 112$

deformity ($n = 05$), auditory neuropathy ($n = 10$), adenoid hypertrophy ($n = 05$), and tongue tie ($n = 10$) were seen along with bilateral hearing loss in children. There was no significant history or any otolaryngological conditions in 900 (88.93%) patients. There were 129 significant medical history/past illness in 112 patients; history of (h/o) CI was reported in 33 (29.46%) (One was a case of known Down's syndrome with congenital heart disease and post VSD closure with mild residual pulmonary hypertension). Delayed milestones were seen in 15 (13.39%). Hypertension ($n = 16$, 14.29%) and diabetes mellitus ($n = 17$, 15.18%) were seen in adult patients (Table 3). Right ear deformity was noted in one.

A total of 12 (1.19%) patients were unable to protrude their tongue, and external deformity and presence of OAEs were noted in four each. Only one patient allergy to penicillin derivatives.

There was no significant family history in 998 (98.62%) patients. Similar complaints in the siblings were reported in 14 (1.38%) patients. Cochlear implantation was done in a sibling of 4 (0.4%) patients.

In pediatric patients, 20 (2.14%) were pre-term babies; five were underweight at birth and were managed in NICU for 15–45 days. About 710 (76.1%) were born *via* lower segment caesarian section, 250 (26.80%) *via* normal vaginal delivery. Details were not available for 52 (5.57%) patients. There was h/o consanguinity in 560 (60.02%) patients, 404 (43.30%) were born to nonconsanguineous couples and details were unavailable for 48 (5.14%).

Right CI was done in 480 (47.43%) patients, left in 318 (31.42%). Bilateral implantation was done in 214 (21.15%) and the bone bridge was done in three. Nose bridge, blind sac closure, and adenoidectomy were done in three each. Reimplantation was required in 30 (2.96%) patients.

The surgeries were performed by two different surgeons, 560 (55.34%) and 420 (41.50%) surgeries respectively, and 32 (3.16%) surgeries as a team.

The surgical procedure included mastoidectomy and posterior tympanotomy. In 625 (61.76%) cases, the cochlea could not be accessed through tympanotomy, and cochleostomy was done.

Of the 1,012 surgeries done, in 967 (95.55%) surgeries complete insertion of electrodes was possible, 25 (2.47%) had incomplete insertion, and information was not available for 20 (1.97%) surgeries.

Duration of hospital stay, postoperatively was 2 days. Duration increased to 7 days or more if it is complicated.

All pediatric patients had an uneventful postoperative period. All were ambulatory (except for 42 infants), with pain score <4, and

Table 4: Complications

Complications	*n*
Major	
Transient chorda tympani syndrome (Cholesteatoma)	01
Flap necrosis	02
Improper electrolyte placement	01
Permanent facial nerve paresis	04
Minor	
Labyrinthitis (Vertigo/dizziness)	04
Ear drum perforation (Hematoma)	01
Incision infection	04

had a clean surgical wound at discharge. The total duration of the hospital stay was three days.

Of 17 (1.68%) complications in adult patients, 8 (47.05%) major complications, and 9 (52.94%) minor complications (Table 4). There was no death reported either due to surgery or its complications.

Superficial wound infection occurred in 4 patients (median 28 days, range 3–358 days) after implantation. It resolved following treatment with topical medications and oral antibiotics.

There was no significant ($p > 0.05$) relationship between the presence of comorbidities and complications.

Discussion

The choice of the type of implant was based on the affordability of the implant by the patient. The complications were reported based on the "International consensus on the reporting of CI complications" and this is to our knowledge the first study in India to use the consensus on CI complications proposed by Hansen et al.[1] and one of the largest studies done in the country on the complications of CI surgery.

Congenital deafness (81.6%) and progressive deafness of unknown etiology are the most common indications of cochlear implantation.[6] It was noted in our study too.

Complications were seen in 1.68% of the surgeries done in our institute. More than half of these complications were minor (52.94%) and self-resolving. We, therefore, consider CI to be a safe procedure.

Ramos et al.[7] reported the rate of complications as 9.8% and classified them as intraoperative, immediate postoperative and postoperative. There was no case of meningitis reported as a complication. A higher rate of complications has been reported by previous studies (10.43–19.9%).[4,6,8–11] Green et al.[12] reported the prevalence of major (6.25%) and minor (25.4%) complications; Implant extrusion, implant sepsis, electrode migration, flap-related problems, and persistent non-auditory stimulation were the major complications. Major complications have been less compared to the minor; similar observations have been reported by previous studies.[6,8,13–15] Wound infections, and device failure are the common complications requiring a surgeon's attention.

The minor complication rates in the present study were similar to that reported by Hansen et al.[1] The differences in complication rates for eardrum perforations, ear canal fenestrations, transient facial nerve pareses, and vestibular neuritis/labyrinthitis did not exceed 3 percentage points. The rate of transient vertigo/dizziness was reported in four patients in our study. Vertigo/dizziness has been one of the common minor complications observed by Hansen et al. (25.0%) and Filipo et al. (29.6%).[1,16] It has also been observed as a subjective episode soon after implantation (34.7%) by Fina et al.[17]

Permanent facial nerve paresis ($n = 04$), flap necrosis ($n = 02$); transient chorda tympani syndrome (CTS), and improper electrode placement in one patient each, were the major complications in our study. Alzhrani et al.[18] reported that delayed onset of facial nerve palsy is common (0.62% vs immediate onset 0.15%), which was due to nerve exposure during the surgery. There was good recovery (80.8%), higher in delayed onset (90.5%) suggesting that it is a transient event. In our study, all three branches of the nerve were involved in permanent facial nerve paresis. The middle ear was found to be normal during surgery and the facial nerve was not reported as injured by the drill or otherwise.

Transient CTS was defined as changes in sense of taste, mouth dryness, or tongue paresthesia that developed postoperatively. An altered sense of taste can occur either in the form of hypogeusia, dysgeusia, or both. Both of our patients had dysgeusia. Flap necrosis and improper electrode placement were seen in two and one patient, respectively. The association between a decrease in taste and olfactory dysfunction post cochlear implantation is well established and reported to be a transient phenomenon.[19] We observed transient CTS in only one patient, lower than that reported by previous retrospective studies (30.8–45.0%).[1,20] We consider this to be an underestimation, as the taste changes were not regularly addressed in our study.

Similar to our study, Ding et al.[21] reviewed 1237 cases of cochlear implantation. Causes for hearing loss included ototoxicity (28.1%) while congenital (14.8%) and inner ear malformation (18.5%). They identified Mondini defect (5.4%) as a causative factor ($n = 05$ in our study). Intraoperative complications included gusher (5.0%) and electrode kinking (2.3%); we did not have any intraoperative complications. Common complications were similar to other studies, including hematoma, wound infection, implant extrusion, and device failure. There was no central nervous system/facial nerve involvement was reported. Li and Zhang[22] analyzed peri-operative complications in 1,397 patients and reported facial nerve palsy ($n = 04$), injury to the external auditory canal and tympanic membrane ($n = 14$), and gusher ($n = 91$) in addition to device-related complications.

Diab et al.[23] have reported technical malfunctioning of the implant (47%), and placement of the active electrode of the device on the hypotympanum (15%). Meningitis, particularly in children, is a complication resulting in few deaths has been reported.[24]

There were no intracranial complications in our study. We found no cases of excessive/sustained bleeding, electrode kinking, dural tear, flap necrosis, mastoiditis, acute pneumolabirynth, pneumocephalus, pneumocoele, meningitis, or death related to implantation. Halawani et al.[25] too report a lower rate of major (0.7%) complications and similar to our study, did not note the above-mentioned ones.

Lower rates (2.8%) of Intraoperative complications have been reported by previous studies, and we report none.[21] The presence of comorbidities has shown no influence on the occurrence of complications in older patients, which is supported by our study too.

Soft-tissue infections at the implant site are a common complication, that may occur even after many years of surgery. Staph aureus, *pseudomonas aerogenosa,* and skin commensals

have been identified as common causative organisms, and in our study as well. There were no long-term complications in our study.

Device failure is the cause of second surgery and re-implantation. Reimplantation was performed in 2.96% of patients in our study. With long-term follow-up with appropriate measures, complications can be reduced.

None of the other complications apart from those mentioned in Table 1 were reported in our study, which is similar to that reported in the literature. This could be due to non-address of symptoms during the postoperative visits at the outpatient clinic, lack of minimum length of follow-up, and lack of proper documentation of the follow-up notes by the medical records. Interestingly, complications in our study occurred mainly in adult patients. Our study is retrospective, hence, we could not analyze the factors that contributed to the complications.

The proposed consensus was employed in our study and we found it easily applicable and with a logical construction. We endorse the notion that an international reporting consensus on CI complications should be established. Further, some added suggestions which may have been previously mentioned by Jeppesen and Faber.[5]

We suggest reporting the surgical technique, describing the follow-up procedure, maintaining patient data from the follow-up visits in electronic medical records and a detailed preoperative evaluation reports available in the patient file.

Further research is warranted, especially regarding CTS, vertigo, and tinnitus, which are possibly more severe in bilateral surgery. These findings are based on small populations and prospective studies with long-term follow-up are essential to clarify the risk and severity of bilateral damage to the vestibular system. The value and relevance of preoperative evaluation are highly debated, as poor maintenance/availability of data. We recommend calculating complication rates as proportions of the total number of implantations, not the number of patients. Calculations based on patient numbers do not take bilateral implantations and re-implantations into account, thus compromising comparability. Further relevant preoperative information should provide patients with knowledge of the risks associated with the impending procedure, making calculations per implantation the clinically relevant measure.

This retrospective study is associated with inherent inaccuracy, as all complications are not necessarily addressed routinely in the outpatient follow-up after surgery. At our center CTS, vertigo/dizziness, tinnitus, and labyrinthitis were generally addressed, but the minor complications, may have been underestimated, and poorly reported and this is a possible bias in our study. Major complications are presumably registered more and consistently.

Controlled prospective studies to investigate causality, and avoid inter-observer variation and bias are required.

Conclusion

Cochlear implantation is a safe procedure with a less, acceptable rate of complications.

However, the lack of availability of well-reported follow-up data has not given a complete insight into the complications, especially minor complications which are generally dealt with in outpatient clinics. An international consensus on the reporting of CI complications is warranted.

Clinical Significance

The complication rate with cochlear implants is within an acceptable range. Infections remain the most common complication. The procedure is safe.

Ethical Approval

Approval has been obtained to publish this article from the Institutional Ethics Committee.

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