COMPLICATIONS OF COCHLEAR IMPLANT SURGERY: A DETAILED STUDY

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ABSTRACT

INTRODUCTION
Cochlear implantation is nowadays the most important means to restore hearing in patients with severe to profound sensorineural hearing loss who are not managed by conventional hearing amplification methods. The cochlear implant helps patients in better understanding and improvement in auditory abilities, speech, and linguistic development. The best results are obtained by doing the implantation at the earliest possible age. As with any other surgical procedure, cochlear implantation also has risks and complications associated with it. It can be minor or major complications. In our study, we have discussed in detail the challenges and complications of cochlear implant surgery.

MATERIAL AND METHODS
This is a retrospective study including 500 patients who were evaluated and operated for cochlear implants at MEHROTRA ENT HOSPITAL, Kanpur, India. All patients were investigated by audiological tests such as aided audiometry, ABR, and otoacoustic emission and found to have severe to profound bilateral SNHL. All patients were radiologically evaluated with CT and MRI. A retrospective review of the patient’s data was done including the patient’s characteristics, surgery, outcome, and complications.

RESULTS
A total of 500 patients were included in our retrospective study out of which 337 were males and 163 were females. All the surgeries were carried out by the same group of surgeons using the standard technique of post-auricular incision and posterior tympanotomy. Patients have been followed up regularly and a close watch was kept on the vital signs, light reflex, pupil size, consciousness, and wound healing. After surgery, patients were kept in the hospital for 2–3 days. Parenteral antibiotics and the compressive mastoid dressing were given, and the patient was discharged with oral antibiotics. We followed up with the patients regularly and managed the complications experienced by them.

CONCLUSION
Cochlear implantation remains a safe and effective surgical procedure for profound sensorineural hearing loss. We have a moderate rate of minor complications and a minimal rate of major complications in relation to other studies. The majority of minor and major complications can be avoided with adequate surgical techniques and can be managed conservatively.

Keywords- Cochlear implants(CI), Minor complications, Major complications, Re-implantation, Cochlear implant surgery.

INTRODUCTION
Cochlear implantation is nowadays the most important means to restore hearing in patients with severe to profound sensorineural hearing...
loss who are not managed by conventional hearing amplification methods.[1] The cochlear implant helps patients in better understanding and improvement in auditory abilities, speech, and linguistic development.[2] The device is an auditory prosthesis designed to stimulate the cochlear nerve and translate acoustical information into electric stimulation. The best results are obtained by doing the implantation at the earliest possible age.[3]

As with any other surgical procedure, cochlear implantation also has risks and complications associated with it. It can be minor or major complications.[4] The minor complications are those which resolve either spontaneously or with conservative management within a few days and the major complications are those which may require hospital admission, revision surgery or long-term management.[5] Although most of the complications are transient, but few may remain permanent and require intensive care and management.

Minor complications include postoperative dizziness, tinnitus, infection, taste changes, transient facial nerve palsy, intraoperative CSF leak, postoperative pain, wound seroma/hematoma, damage to the tympanic membrane; injury to the posterior wall of the external acoustic meatus during surgery, facial swelling, intra and post-operative bleeding, surgical emphysema, minor electrode mal-position, skin ulceration, granulation tissue bleeding, and pinna ulceration.[6]

Major complications include facial nerve stimulation, poor response of the auditory nerve, electrode extrusion, device migration, infection, skin flap dehiscence, electrode misplacement, device failure, permanent facial paralysis, and meningitis. The aim of our study is to assess the incidence of complications at our centre and the basis to reduce the incidence of these minor and major complications.[7]

**MATERIAL AND METHODS**

This is a retrospective study including 500 patients who were evaluated and operated for cochlear implants at MEHROTRAENT HOSPITAL, Kanpur, India. All patients were investigated by audiological tests such as aided audiometry, ABR, and otoacoustic emission and found to have severe to profound bilateral SNHL. All patients were radiologically evaluated with CT and MRI. A retrospective review of the patient’s data was done including the patient’s characteristics, surgery, outcome, and complications. All patients consenting to the study were included in this study.

**RESULTS**

A total of 500 patients were included in our retrospective study out of which 337 were males and 163 were females. All the surgeries were carried out by the same group of surgeons using the standard technique of post-auricular incision and posterior tympanotomy.

**Post-operative care**

Patients have been followed up regularly and a close watch was kept on the vital signs, light reflex, pupil size, consciousness, and wound healing. After surgery, patients were kept in the hospital for 2–3 days. An x-ray was done intraoperatively to verify the position of the electrode array. Parenteral antibiotics and the compressive mastoidectomy were given, and the patient was discharged with oral antibiotics. Sutures were removed on the tenth postoperative day and wound status was assessed for any complications. We followed up with the patients for 3 years regularly.
Minor Complications
Minor complications include postoperative dizziness, tinnitus, mild infection, chorda tympani nerve injury, transient facial nerve palsy, intraoperative CSF gusher, postoperative pain, and wound seroma/hematoma. (Figure 1) Most of these complications appear immediately after surgery and resolve completely within a few days.

Figure 1: Occurrence Rate of Minor Complications (n=500)

Postoperative Dizziness
Postoperative dizziness is one of the most common complications post-surgery. The dizziness occurs during the first 3 to 4 days in the majority of the patients after surgery and it regresses itself over time without any medications. The caloric test before surgery indicated normal or near-normal responses in these patients, and the occurrence of dizziness after surgery depended on the vestibular function of the ear operated on. Because small children cannot explain the dizziness, they may simply have recurrent vomiting for 1-2 days after the surgery.

Continuing dizziness or unsteadiness may be a sign of unilateral vestibular deficits that occurred after cochlear implantation. If the only ear with vestibular function is operated, it may cause bilateral vestibular deficiency.[8] In older patients, compensation takes more duration than in younger patients. The patient may complain of dizziness or unsteadiness for a long time.

Preoperative assessment of the vestibular function is important to avoid this complication.

Associated Meniere disease patients may have recurrent vertigo even after surgery. Postoperative dizziness can be minimized with careful maneuvering during cochleostomy and electrode insertion. In our study, out of 500 patients, 131 patients (26.2%) complained of dizziness postoperatively.

Tinnitus
Tinnitus complaint can be most commonly seen in patients who complained of it preoperatively. The tinnitus usually occurs only for a few days post-surgery and subsides without any treatment. When patients start to use the CI, the loudness of tinnitus decreases in most patients because of the masking effect.[9] In addition, in the large number of patients tinnitus decreases even after CI is turned off. Explaining these characteristics of tinnitus to patients would provide more relief than the use of medication. In our study, out of 500 patients, 28 patients (5.6%) complained of tinnitus postoperatively.

Infection
Earlier the prevalence of infection and skin flaps problems was high. Now as the small incision surgery has become popular, prevalence of infection and skin flap problems has grossly reduced. The use of perioperative antibiotics and routine prophylaxis can prevent infection in most cases. Early examination and management of infection should be of utmost importance. In our study, out of 500 patients, 15 patients (3%) complained of infection and skin flap problems postoperatively.

Chorda tympani nerve injury
Chorda tympani nerve injury may present as reduced sensation, complete loss of taste, or numbness of the tongue. The chorda tympani
nerve must be carefully handled during the facial recess approach of cochlear implant surgery, but minor damage is sometimes inevitable, but the symptoms regress itself within the few weeks and permanent complaints of such taste disturbances are very rare. In our study, out of 500 patients, 32 patients (6.4%) complained of taste changes postoperatively.

**Transient Facial nerve palsy**

Transient facial nerve palsy is a rare occurrence but a major annoyance. It can most likely occur due to the heat from the drilling, or abnormal anatomy, or another unknown causes. Most of the time facial nerve palsy recovers itself without any medications. The surgeon should always try to delicately handle the facial nerve during the cochlear implant surgery. Electrophysiologic studies such as electroneurography and evoked electromyogram can help predict the prognosis. In our study, out of 500 patients, 12 patients (2.4%) complained of facial palsy postoperatively and all the patients recovered completely from facial palsy within a few months.

Mostly facial nerve palsy occurs in malformed ears, or in which the anatomical course of the facial nerve is different from that in normal ears. Even in ears with normal anatomy, heating of the facial nerve during the facial recess approach may result in reversible or permanent damage to the nerve. (Figure 2) Immediate paralysis indicates nerve injury, and decompression or repair surgery should be scheduled urgently. The facial nerve function mostly recovers in the majority of cases but complete recovery may not be achieved in some severe cases. Surgical correction may be required for conditions such as a very narrow eyelid opening.

**Figure 2:** Cochlear implant patient with facial nerve palsy

**Intraoperative CSF gusher**

CSF gusher occurs mostly due to congenital anomalies of the inner ear. In our study, out of 500 patients, 18 patients (3.6%) had intraoperative CSF gusher and the leakage was stopped using surgical and soft tissue intraoperatively and patients recovered completely postoperatively.

**Postoperative Pain**

Pain at the site of incision for cochlear implant surgery is quite common postoperatively. It regresses itself within 3-4 days of surgery. In our study, out of 500 patients, 98 patients (19.6%) complained of postoperative pain and were managed conservatively.

**Wound seroma/hematoma**

A small seroma/hematoma is often managed via local pressure dressing, antibiotics, and symptomatic treatments. Large seroma/hematoma may require additional surgical drainage under complete aseptic conditions. (Figure 3) In our study, out of 500 patients, 30 patients (6%) complained of seroma/hematoma postoperatively and all recovered completely with conservative management.
electrode on the cochlear outer wall may also be the cause. In this case, facial nerve stimulation may occur in several months or years after using cochlear implant. The most likely source of facial stimulation is due to the electrodes which are located beneath the labyrinthine portion of the facial nerve. (Figure 5) The symptom subsided after reprogramming the selective electrode and complete resolution was seen in all patients, but selective electrode reprogramming can impair hearing also. In addition to this, some studies have suggested administration of botulinum toxin but it requires repeated injections. In our study, out of 500 patients, 4 patients (0.8%) complained of facial nerve twitches and were managed conservatively with selective reprogramming of electrodes.

Figure 4: Occurrence Rate of Major Complications (n=500)

Facial nerve stimulation
Facial nerve stimulation while using cochlear implants occurs in a significant number of patients, although its incidence is variable in previous studies ranging from 0.31% to 14%. If facial twitching appears immediately after switching on the device it may be due to the inadequate partition between the facial canal and the superior segment of the cochlear basal turn. Physical pressure induced by the straight
useful for detecting whether the auditory nerve is a plastic, poor response of the auditory nerve often occur seven in patients with a normally shaped auditory nerve. Reimplantation on the contralateral side or the use of an auditory brainstem implant can be a treatment option. In our study, out of 500 patients, 2 patients (0.4%) complained of poor response of the auditory nerve postoperatively and were reimplanted on the contralateral side.

**Electrode Extrusion**
This complaint includes slipping out of the electrode from the cochlea, or electrode lead extrusion from the tympanic membrane or from the external ear canal. It can be sudden (due to trauma) or gradual over time. (Figure 6) The surgeon should take the precaution that if the external bony canal has become thin during the facial recess approach, it should be repaired with cartilage or bone pate, and electrode array fixation in the buttress portion may also help in preventing extrusion.[1] In our study, out of 500 patients, 2 patients (0.4%) complained of electrode extrusion postoperatively and were confirmed by postoperative CT, and these patients were managed surgically under GA with reinsertion of electrodes.

**Device Migration**
In association with electrode migration, device (magnet) migration tends to occur towards the auricle. The device migration could be due to sudden trauma or infection. Every case of device migration does not require revision surgery, but reimplantation may be needed in some cases where the implant body comes too close to the **behind the ear processor**. (Figure 7) Reimplantation surgery should be performed under GA for preserving the electrode array in its former place. Surgical techniques, such as deeply drilled well and permanent suture fixation, can prevent this adverse effect. In our study, out of 500 patients, 5 patients (1%) complained of device migration, out of which 3 were managed conservatively and the rest 2 were reimplanted surgically.

**Figure 6:** Showing cochlear implant electrodes in the external ear canal.

**Figure 7:** Device migration and flap breakdown after infection.
Infection
Infections of the subcutaneous tissue or inner ear are rare unless the operated ear features chronic discharge. It mostly occurs in younger age groups in lower socioeconomic strata and within 3-4 months of surgery. The most common causative agent was found to be Staphylococcus aureus. In our study, out of 500 patients, 16 patients (3.2%) complained of infection postoperatively, out of which 10 were managed conservatively and the rest 6 were managed surgically. Additionally, meningitis developed in 3 patients and was managed with antibiotics, and no fatality due to CI surgery was reported.

Perioperative infusion of antibiotics diminishes the occurrence of postoperative infection. Post CI surgery meningitis may be prevented by avoiding the use of artificial devices around or inside the cochleostomy site. In addition, the surgical guidelines recommended the preoperative vaccination for pneumococcus. Recurrent infection can lead to flap necrosis or skin breakdown. Revision surgery should be performed at the earliest with adequate conservative management.

Electrode misplacement
In patients with normal anatomy, the insertion of electrodes into the cochlea is relatively uncomplicated. However, in an ossified or anomalous cochlea positioning of the electrode is difficult. We believe this complication tends to occur in the initial few cases, with abnormal anatomy, but when the surgeon gets thoroughly familiar with the cochlear anatomy and with experience this complication subsides gradually. Intraoperative X-ray examination and neural response telemetry should be conducted in every patient to avoid this complication. Immediate revision surgery is also mandatory for resolving this problem. In our study, out of 500 patients, 2 patients (0.4%) experienced electrode misplacement, and immediate revision surgery was performed.

Device failure
This is the rarest complication currently. There are 2 kinds of device failure, one is caused by malfunctioning of the internal device and the other by direct trauma. Hardware failure are now becoming less as the manufacturers improve control for constructing the device. In our study, out of 500 patients, 1 patient (0.2%) complained of device failure due to direct trauma and revision surgery with a new cochlear implant was performed.

DISCUSSION
Cochlear implantation has made great progress in recent years, and postoperative complications have reduced significantly with the improvement of surgical equipment and techniques employed by surgeons. The cochlear implant has changed the future perspective of profoundly deaf children and adults. CI has enabled congenital deaf children to use speech as their primary route of communication by providing sufficient hearing sensations.[12]

It has now become important to evaluate the safety and efficiency of such procedures to improve them and reduce the incidence of complications. In our study, we have a moderate rate of minor complications and a minimal rate of major complications.[13] The overall rate of complications was 5.28% (Minor complications 9.1% and Major complications 0.91%). Venailet al.[14] reported an overall rate of complication to be 16% in their study.

In our study, we had 131 cases (26.2%) who had postoperative vertigo out of 500 cases who underwent CI surgery. Jeppesen and Faber[15] in
a study of 308 cases reported 29.5% of transient vertigo. Júnior et al. [16] reported 6 cases (2.4%), out of 250 cases, who had postoperative vertigo. Migirov et al. [17] reported postoperative vertigo(10%)in 28 cases, out of 300 cases.

In our study, we reported that 32 cases (6.4%) had chorda tympani injury out of 500 cases that underwent cochlear implantation. Jeppesen and Faber [15] in a study of 308 cases operated for cochlear implantation reported 30.8% of chorda tympani nerve injury. Ajalloueyan et al. [18] in a study of 262 cases operated for cochlear implantation reported 3% of chorda tympani nerve injury. Migirov et al. [17] operated 300 cases of CI by SMA and reported one case of chorda tympani nerve injury (0.3%).

In our study, out of 500 cases who underwent cochlear implantation, 12 cases (2.4%) had facial nerve paralysis. Transient facial paralysis was present in all these 12 patients and facial function became normal within a few months of the operation. Migirov et al. [17] reported facial nerve paralysis in 2 cases (0.6%) out of 300 cases. All of them had a total recovery. Ajalloueyan et al. [18] reported that in a study of 262 cases operated by both approaches, 1% had facial nerve paralysis.

In our study, out of 500 cases who underwent CI surgery, there were 18 cases (6.1%) that had CSF leakage during surgery. The most common cause was congenital anomalies of the inner ear. Li et al. [19] reported that 3 patients (1.15%) out of 260 cases had severe CSF gushers during the surgery. Gheorghe et al. [20] reported that 2 patients out of 79 patients had severe CSF gushers.

In our study, there were 30 cases (6%) who had wound seroma/hematoma out of 500 cases who underwent CI surgery. Brito et al. [7] in a study of 550 cases reported that 3 cases (0.5%) had wound hematoma.

In our study, we reported 5 cases (1%) had device migration out of 500 cases who underwent cochlear implantation surgery out of which 3 were managed conservatively and the rest 2 were reimplanted. Jonas Jeppesen and Faber [15] reported electrode migration in 1.3% of patients out of 308 cases. Brito et al. [7] in a study of 550 cases reported that problems during electrode bundle insertion were the most frequent complication, happening in 21 (3.8%) cases. Ajalloueyan et al. [18] reported device migration in 2% of cases out of 262 cases that required repositioning. Multiple causes could be there for device migration but, the canal wall reconstruction, split bridge technique, or tight packing around the cochleostomy window will surely help in reducing the occurrence of this complication.

In our study, there were 16 cases of major wound infection (3.2%) after surgery. Ajalloueyan et al. [18] reported that after CI surgery 2 cases had wound infection (0.8% out of 262 cases). Jeppesen and Faber [15] reported 3.6% of patients had wound infections out of 308 patients. Raghunandan et al. [3] reported that 6 patients developed flap infections out of 300 cases after CI surgery.

In our study, there were 3 cases (0.6%) that had post-implantation meningitis. Green et al. [6] reported no cases of meningitis out of 240 operated CI patients. Ajalloueyan et al. [18] reported that 0.8% had post-implantation meningitis out of 262 CI operated patients. Júnior et al. [16] reported no cases had post-implantation meningitis out of 250 operated CI patients.

In our study, we found 1 case (0.2%) had a device
failure out of 500 cases that underwent cochlear implant surgery. Kevin et al. [21] reported 7.8% had device malfunction out of 805 cases. Ajalloueyan et al. [18] reported device malfunction in 1% out of 262 operated CI cases. Jeyakumar and Clary [22] reported a 3.0% device failure rate out of 143 pediatric cochlear implant cases.

CONCLUSION
Cochlear implantation remains a safe and effective surgical procedure for profound sensorineural hearing loss. We have a moderate rate of minor complications and a minimal rate of major complications in relation to other studies.[23] The majority of minor and major complications can be avoided with adequate surgical techniques and can be managed conservatively.

DECLARATION
Ethics approval and consent to participate: The study was approved by Organisational Ethics committee.

Conflict of Interests- The authors declares that there are no conflicts of interest.

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