OTOLOGY

Soft tissue reactions following cochlear implantation

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Abstract

Introduction Cochlear implantation is a boon to children with hearing loss. Rarely, it can be associated with complications.
Soft tissue reaction can be a particularly distressing complication.
Materials and methods The study was conducted on all patients presenting with soft tissue reaction post-cochlear implant
in a tertiary care referral institute from March 2011 to June 2018. We graded the severity of soft tissue reaction as per the
severity and then managed these patients accordingly.
Results Thirty-five patients were included in this study. Grade 1 had 12 patients, grade 2 had 9, grade 3 had 4 and grade 4
had 9 patients. Grade 1, 2 and 3 reactions were managed conservatively, while grade 4 required surgery. The incidence of
explantations increased with the grade severity.
Conclusion Soft tissue reaction post-cochlear implant is a rare, but distressing complication. Grading and analyzing them
can help us manage them in a better way.

Keywords Cochlear implantation · Soft tissue reaction · Revision surgery

Introduction

Cochlear implantation is an established treatment for
patients with bilateral severe to profound sensorineural
hearing loss. The results of cochlear implantation in a good
candidate are extremely gratifying in terms of hearing and
speech. Sometimes, the patients develop a complication,
which hampers the results that at times even require an
explantation [1]. Surgical complications can be classified
into major and minor complications (Cohen and Hoffman)
[2]. Major complications include flap necrosis, implant
extrusion, hematoma formation, meningitis, misplaced elec-
trode array, magnet displacement, etc. Minor complications
include postoperative pain, facial nerve stimulation, paresis
or palsy, chorda tympani nerve damage, dizziness, etc. One
of the worst complications is soft tissue reaction follow-
ing cochlear implantation. This can be in the form of small
localized inflammatory reaction, leading to delay in implant
use or stoppage of implant usage for some time; or it could
be a severe infection, which may lead to extrusion and in
many cases require removal of the implant. Local skin com-
plications rates, including ulcer, infection and wound dehis-
cence, are reported as 1.3–5.3% [1, 3]. We present a series
of patients who presented to our center with inflammation or
infection at implant site after cochlear implantation.

Materials and methods

This study was conducted from March 2011 to June 2018
in the ENT Department of SMS Medical College and Hos-
pital, Jaipur, India, a tertiary care referral hospital. During
this period, 413 patients underwent cochlear implantation
in our institute. All the patients with soft tissue reaction fol-
lowing cochlear implantation were included in this study.
These included those who underwent surgery at our center
or referred to us after primary surgery at some other place.
Patients with all types of soft tissue reactions ranging from
those with edema/collection at implant site to those with skin
necrosis and implant extrusion were included. We graded
these patients into four grades as described in Table 1.

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Table 1 Grading for soft tissue reaction following cochlear implantation

Grade	Features
1	Intermittent swelling, no pain (or tenderness)/erythema/discharge, skin intact
2	Swelling/pain (or tenderness)/erythema present, no discharge, skin intact
3	Swelling/pain (or tenderness)/erythema/discharge present, skin intact but macerated
4	Exposed implant with skin necrosis

The patients were managed as per the grading of skin reaction (Table 2). For grade 1, only pressure dressing and anti-inflammatory drugs were used. For grade 2, antibiotics (amoxycillin–clavulinic acid) were added to the management. In patients with grade 3 reactions, culture-directed antibiotics were used along with twice a day dressing. In grade 4 with exposed cochlear implant, culture-directed medicines were administered and a rotation flap was used to cover the implant as soon as possible. If the rotation flap failed and the skin necrosed again, the implant was explanted.

Results

Thirty-five patients who presented to the ENT OPD of our institute with some form of skin reaction after undergoing cochlear implant at our center or referred to us after undergoing cochlear implant somewhere else were included in the study. The age group of these patients was between 3 and 8 years. One of the patients, who was a known case with Rubella syndrome, also had bilateral complete vision loss. The general condition of the patients was otherwise good. Twelve out of 35 were referred to our center after primary surgery at some other place. Out of these, 12 presented with only intermittent swelling (grade1), while 10 also had some pain and erythema (grade 2). All these were managed conservatively; however, one patient each with grade 1 and 2 reactions had to be explanted. Thirteen patients were in grade 3 and 4. Four of them were in grade 3 to start with and then progressed to grade 4. So, we had four patients in grade 3 and nine in grade 4. Two patients of grade 3 required explantation despite conservative management. For grade 4 the conventional treatment has been explantation, but there are few reports of salvage surgery [4–7]. We advised a rotation flap with relocation of the implant to all patients in grade 4 and those of grade 3 who did not improve conservatively.

Two out of nine in grade 4 opted against getting a revision surgery and were explanted. Seven patients underwent rotation flap surgery and four of them could be salvaged. The culture of five of these patients showed coagulase-negative *Staphylococcus* and two patients had *Pseudomonas aeruginosa*. All those who had developed implant extrusion post-trauma (two) could be salvaged. The steps of this surgery were as follows. The incision used for the surgery was based on the previous incision and the technique used. Therefore, for a posterior tympanotomy technique, an inferiorly based broad pedicled musculocutaneous flap was raised, and for a previously done Veria technique, the incision was extended posteriorly and inferiorly so that an anteroinferior broad-based rotation flap was elevated. It is important to liberally excise all the infected skin, subcutaneous tissue, muscles, granulations and capsule surrounding the implant. The bio-film present should be curetted out. Many a times, infected tissue is seen to travel along the electrode array, which should also be removed gently without damaging the array. After elevating the first flap, a separate superiorly based periosteal flap was elevated. A fresh bed was made for the implant. In all the cases, which were successful, the bed was made inferior to the previous one. This helped to keep the implant away from the previously infected area as well as from the new incision line. Then the implant was lifted off from its previous bed and placed in the new bed. In two of our cases, we found that Prolene suture had been used by the previous surgeon to anchor the implant to its bed. As Prolene is a non-absorbable suture, it remains there and many people have noted stitch abscess on its knot area. We therefore use only Vicryl for this purpose, if we plan to anchor its base, which usually dissolves within 2 months. Lately, we have stopped tying the implant to its bed if we get a good bone depth. In both the cases, we removed the Prolene suture and then used Vicryl to tie the implant to its new bed. The fantail of electrode array was given an extra covering in the form of harvested conchal cartilage, as we found that this was the

Table 2 Management protocol according to the grading

Grade	Management
1	Pressure dressing, anti-inflammatory drugs
2	Pressure dressing, anti-inflammatory drugs + amoxicillin–clavulinic acid
3	Twice a day dressing, culture-directed antibiotics
4	Culture-directed medicines and rotation flap surgery ± explantation

area which was most commonly exposed. Thorough washing of the whole area and debridement of any suspicious tissue were done. The implant was then covered in the form of double-breasted flaps of periosteum and musculocutaneous layers. The wound was closed in two layers and pressure dressing was given with extra pressure over the site of previous bed, as that has a higher chance of fluid collection due to a potential space caused by the defect in the bone. Suture removal was done after 2 weeks. Patients were put on iv antibiotics for a week (ceftriaxone and amikacin), oral ciprofloxacin for 2 weeks and rifampicin for 4 weeks. The external processor was used only after 4 weeks.

Discussion

Cochlear implantation is a safe and effective method for rehabilitation of patients with bilateral severe to profound sensorineural hearing loss [8]. Complications are rare in cochlear implant surgery, but when they occur it can be tough to manage [9]. Cohen and Hoffman have written quite a few articles on complications post-cochlear implant and their classification of complications into major and minor is widely accepted [2, 10, 11]. They defined major complications as those that require surgical intervention or hospitalization and minor complications as those that are managed conservatively without hospitalization.

Infection is a major concern in any surgery, especially cochlear implantation. The overall incidence of infections reported in the literature ranges from 1.7 to 16.6% [9]. Postoperative surgical site infection has been reported in 1–12% of patients who have undergone cochlear implantation [12, 13].

Soft tissue reactions to the implant can be in the form of swelling, pain, erythema, discharge or skin necrosis. Severe forms may require explantation. It is difficult and distressing to manage these complications and quite a few of these patients land up with explantation. This is especially of concern in government-funded or philanthropic programs where the new implant may not be made available easily. We have devised a grading for these soft tissue reactions according to which these reactions can be graded, so that we can achieve uniformity while reporting and the management can be planned in a better way.

Grade 1 (Fig. 1) included those patients who presented with intermittent swelling at the implant site without any pain or discharge or erythema after variable duration of surgery. All these were managed with non-usage of implant for a week with pressure dressing and steroids (0.5 mg/kg prednisolone). No aspiration was done in any of these patients. Two of those 12 patients needed the management more than once. One of the 12 patients with grade 1 reaction did not improve and had to be explanted.

Fig. 1 Grade 1 intermittent swelling, no pain and erythema skin intact

Fig. 2 Grade 2 swelling, pain, erythema present and skin intact

Grade 2 (Fig. 2) included those patients who presented with swelling, pain and erythema at the site of implant without any discharge. All these patients were started on similar management protocol as grade 1, but with addition of amoxycillin–clavulinic acid for 2 weeks along with analgesics. Also, patients were asked not to use implant for a 2-week period. One patient out of ten had to be explanted.

All patients who had some form of discharge, even though skin appeared grossly intact but macerated, were included in grade 3 skin reaction (Fig. 3). Implant usage had to be stopped for a variable duration from patient to patient varying from 2 weeks to 6 weeks. Culture-directed antibiotics were used with regular twice a day dressing. To start with, we had eight patients in grade 3, but four of them progressed within a couple of days to grade 4. So we had four patients in grade 3, who were managed without salvage surgery. Two of them had to be explanted, while the other two underwent explantation.

In total, we had nine patients in grade 4 with skin flap necrosis and implant extrusion (Fig. 4). All of them were counseled for salvage surgery in the form of rotation flap and relocation of the implant; however, two patients opted against it and were explanted. The implant could be salvaged in four out of seven who had undergone salvage surgery and three needed explantation. There have been few techniques, which have been discussed in literature to salvage an extruded implant; however, none has been well accepted. There are people who have used other types of flaps and

Fig. 4 Grade 4 exposed implant with skin necrosis

even free flaps for this purpose [6, 7]. Manuka honey and tea tree oil have also been reported to be effective in view of their activity against biofilms [4, 14].

The reasons for soft tissue reaction can be patient related, surgeon related or implant related. One of the major risk factors for this has been considered to be the shape and thickness of the skin flap. The skin flap needs to be thin, because a thick skin flap is not able to hold the external device by magnetic force. The majority of implant companies advise keeping this thickness less than 6 mm. Excessive thinning of this flap is a major reason for wound breakdown later on. The type of incision used determines the shape of the flap and this was a major reason for anteriorly based C-shaped flap to go into disrepute [3].

Implant thickness is another reason for soft tissue reactions. The more the thickness or maximum vertical projection of the implant, the higher are the chances of it getting extruded due to pressure on the thinned out skin.

Maintaining absolute sterilization is an integral part of cochlear implant surgery and any lapse in this can lead to infection and then skin necrosis, leading to explantation. Some literature has been published on silicone and/or platinum allergy or foreign body response, leading to extrusion [15, 16]. This should be kept in mind while dealing with patients of culture-negative extrusion. However, in the author's view, infection still remains a major reason, with hypersensitivity being probably a minor issue in terms of numbers.

Fig. 3 Grade 3 swelling, pain, erythema present and skin macerated

Children while playing can have trauma to the implant site leading to reactions on the skin. This is of special importance in hyperactive children. In our series, we found that post-trauma skin wound children do better than those who developed problems because of infection per se.

Conclusion

Soft tissue reactions after cochlear implant can vary from intermittent swelling to frank skin necrosis and implant extrusion. Though rare, it is a distressing complication. Grading these soft tissue reactions can help better analyze, plan and then manage these complications.

Compliance with ethical standards

Conflict of interest All the authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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