The Journal of Laryngology & Otology

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Complications after cochlear implantation in adult patients: a retrospective study

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Abstract

Objective. To examine the complication rate in adult patients during and after cochlear implantation.

Methods. A retrospective chart review was conducted of patients who had undergone cochlear implantation at a tertiary referral centre between 2009 and 2018. All complications and their treatments were categorised as either minor or major, as well as intra- or post-operative.

Results. The records of 392 patients with 395 implants were reviewed. The mean follow-up period was 89 ± 65.5 months (range, 6–408 months). The mean age of patients was 46 ± 15.2 years (range, 19–84 years). Sixty-two patients (16 per cent) had minor complications and 31 (8 per cent) had major complications.

Conclusion. Although cochlear implantation has the potential for significant intra- and post-operative complications, the actual complication rate is relatively low, and it can therefore be considered a safe procedure.

Main Article

Dr A Dalgic takes responsibility for the integrity of the content of the paper

Abstract of the study presented at the 11th Asia Pacific Symposium on Cochlear Implants and Related Sciences, 19–22 September 2017, Famagusta, Cyprus.

Cite this article: Dalgic A, Bozkurt EB, Aliyeva A, Görgülü E, Ceylan ME, Edizer DT, Olgun L. Complications after cochlear implantation in adult patients: a retrospective study. *J Laryngol Otol* 2023;**137**:259–262. https://doi.org/10.1017/S0022215122001827

Accepted: 15 July 2022
First published online: 11 August 2022

Key words:
Hearing Loss; Cochlear Implantation; Adults

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Introduction

Cochlear implantation improves hearing levels and the overall quality of life of patients with profound bilateral hearing loss.[1–4] Although cochlear implantation is considered a relatively safe procedure, it may lead to complications during or after surgery.

In a seminal article published by Cohen and Hoffman in 1991 on surgical issues related to cochlear implantation,[5] a system for classifying complications as major or minor was reported.[6,7] Major complications are those that are life-threatening and/or necessitate revision surgery. Minor complications are those that spontaneously resolve with minimal treatment. Details of the classification used are included in the Methods section below.

Complications of cochlear implantation include: scalp infection and necrosis; haematoma and seroma; major skin flap loss; meningitis; facial nerve injury; electrode insertion problems; and secondary cholesteatoma development.[8]

The present study aimed to examine the complication rate, and in turn the safety of the procedure, in adult patients during and after cochlear implantation.

Materials and methods

We retrospectively reviewed the charts of patients who had undergone cochlear implantation at a tertiary referral centre between 2009 and 2018. Patients older than 18 years were included. We noted their demographic characteristics and medical history, including occurrence of hearing loss (i.e. prelingual, perilingual or postlingual, congenital or acquired), oto-microscopic findings, audiological evaluation results, follow-up duration, complications during and after the operation, and the requirement and reasons for revision surgical procedures. We obtained ethical approval from the local ethics committee (decision number: 17102018/02).

In this study, we classified post-operative complications as major or minor based on the system reported by Cohen and Hoffman.[5] Intra-operative difficulties or complications were included too. Cohen and colleagues classified major complications as: death; meningitis; surgery without reimplantation; and tinnitus, facial stimulation and pain that could not be alleviated. Minor complications included: transient facial paralysis; haematoma and infections that resolve without surgery; and tinnitus, facial stimulation and pain that did subside following electrode reprogramming.

Statistical analysis was performed using SPSS for Windows software, version 20.0 (SPSS, Chicago, Illinois, USA). Descriptive statistics (arithmetic mean, median, minimum, maximum, standard deviation and standard error) were calculated based on the obtained data. Pearson's chi-square analysis was used for between-group comparisons. *P*-values of less than 0.05 were considered statistically significant.

Results

The records of 392 patients with a total of 395 implanted ears were included in this review. For percentages, the number of patients, and not ears, was used as the denominator. The patients included 212 (54 per cent) males and 180 (46 per cent) females. Right-sided implantation was performed in 240 patients (60 per cent), left-sided implantation in 149 (40 per cent) and bilateral implantation in 3 (0.7 per cent). The mean follow-up period was 89 ± 65.5 months (range, 6–408 months). Mean patient age was 46 ± 15.2 years (range, 19–84 years). Hearing loss was reported to be prelingual in 78 patients (20 per cent), perilingual in 33 (8 per cent), and postlingual in 281 (72 per cent). Hearing loss was congenital in 15 patients (4 per cent), acquired in 150 (38 per cent) and undetermined in 227 (58 per cent). The full demographic data and patient characteristics are presented in Table 1.

There were 15 patients (4 per cent) with cerebrospinal fluid (CSF) leaks, in the form of a 'gusher' or 'oozing', of which 12 (3 per cent) had inner-ear anomalies. The most common of these anomalies was a large vestibular aqueduct, which was observed in eight patients (2 per cent). Two patients had incomplete partition type 2 and two patients had incomplete partition type 3 inner-ear malformations. No other complications were reported in this group. There was a statistically significant difference in the rate of CSF gushers between the patients with inner-ear anomalies (92.3 per cent) and those without (0.8 per cent) ($p < 0.01$).

The list of complications, as categorised into intra- and post-operative and minor and major complications, are presented in Table 2. In this study, the post-operative complication rate was 24 per cent, including post-operative minor complications in 62 patients (16 per cent) and post-operative major complications in 31 (8 per cent) (Table 2). Intra-operative minor complications occurred in 34 patients (9 per cent); there were no intra-operative major complications. Fifteen patients (4 per cent) had a CSF gusher or oozing, of which 14 were treated conservatively. One patient underwent revision surgery for a CSF gusher; this patient was also included in the post-operative major complication group. Damage to the facial nerve canal occurred in four patients; however, these patients did not have facial paralysis. Damage to the external ear canal was observed in seven patients (2 per cent), and was treated by performing bone dust or cartilage grafting during the operation. Two patients had damage to the chorda tympani and suffered taste problems on the operation side of their tongues. Iatrogenic damage to the cochlear implant electrode array occurred in one patient, which was managed using a backup implant.

Table 1. Demographic data and characteristics of study

Parameter	Value
Sex (*n* (%))	
– Male	212 (54)
– Female	180 (46)
Side (*n* (%))	
– Right	240 (60)
– Left	149 (40)
– Bilateral	3 (0.7)
Follow-up period (mean ± SD (range); months)	89 ± 65.5 (6–408)
Age (mean ± SD (range); years)	46 ± 15.2 (19–84)
Type of hearing loss (*n* (%))	
– Prelingual	78 (20)
– Perilingual	33 (8)
– Postlingual	281 (72)

SD = standard deviation

Discussion

The development of better technologies and improved surgical techniques have led to a gradual decrease in cochlear implantation complications over the years. Nevertheless, the literature still contains inconsistencies regarding the rate of complications. One study reported decreased complication rates in adults.[9] Paediatric patients have significantly higher complication rates than adults, but only for post-operative minor complications.[10,11]

Farinetti *et al.*[10] reported a post-operative minor complication rate of 21 per cent and a post-operative major complication rate of 5 per cent in a report on 168 patients. Ciorba *et al.*[12] reported a post-operative complication rate of 15 per cent (21 of 141 adult patients) for all complications. While analysing 4969 implantations, Hoffman and Cohen[7] reported the major complication rate as 7 per cent and the total complication rate as 12 per cent, which is consistent with the results of this study.

Table 2. Intra- and post-operative minor and major complications

Complications	Cases (*n* (%))
Intra-operative minor	34 (9)
– CSF 'gusher' or 'oozing'	15
– External ear canal damage	7
– Haemorrhage	5
– Facial canal damage	4
– Chorda tympani loss	2
– Iatrogenic damage to electrode	1
Intra-operative major	0 (0)
Post-operative minor	62 (16)
– Post-auricular oedema	20
– Vestibular disorders	19
– Facial stimulation	8
– Wound infection	8
– Haematoma	4
– Facial paralysis	3
Post-operative major	31 (8)
– Software failure	17
– Electrode migration	5
– Chronic otitis media	3
– Skin flap failure	1
– Implant body migration	1
– Severe infection	1
– Trauma	1
– CSF gusher	1
– Magnetic attachment problem	1

CSF = cerebrospinal fluid

https://doi.org/10.1017/S0022215122001827 Published online by Cambridge University Press

Post-operative minor complications occurred in 62 patients (16 per cent). The most common post-operative minor complication in this study was transient oedema, which occurred in 20 patients. It developed over the internal receiver transmitters and resolved within 10 days with a tight dressing. We believe that post-auricular transient oedema is more likely to develop in patients who do not follow post-operative recommendations, including head elevation.

In most studies, the most common post-operative minor complication reported was vestibular dysfunction.[10,13–16] Vestibular dysfunction was reported in 19 patients (5 per cent) in this study. Sixteen patients (4 per cent) had dizziness, which resolved within 2–3 days following surgery. There were no cases of delayed dizziness. Early trauma associated with electrode insertion, acute serous labyrinthitis, foreign body rejection, endolymphatic hydrops and intra-operative perilymph loss were considered as reasonable possibilities for post-operative dizziness.[17]

Three patients complained of early tinnitus, which did not prevent them from using the implant. Electrode insertion into the basal part of the cochlea can result in tinnitus as well as delayed tinnitus.[18] Eight patients had facial stimulation, which happens when the electrode's electrical current emits to the cochlea and adjacent structures. All eight patients were successfully managed by reprogramming the cochlear implant.

Eight patients (2 per cent) had wound infections, which were treated via appropriate intravenous antibiotic treatment. Four patients (1 per cent) had haematoma in the early post-operative period, which was treated conservatively. Lima Junior *et al.*[13] reported the minor haematoma rate as 0.4 per cent in their study. Reviews of the literature have revealed that the incidence of haematoma is very low in adult populations,[19,20] similar to the results of this study. Three patients developed temporary facial paralysis, which is typically associated with oedema or transient nerve injury during drilling or manipulation. This is consistent with the findings of Roberts *et al.*[16] and Farinetti *et al.*,[10] who reported two and one cases, respectively.

Post-operative major complications were observed in 31 patients (8 per cent). Software failure of the device was the most common major complication and was observed in 17 patients (4 per cent). In their review, Terry *et al.*[19] observed device failure in 507 of 14 704 patients with cochlear implantation (3 per cent), which was the second most common complication. Farinetti *et al.*[10] reported 7 device failure cases in 21 patients with major complications. Ciorba *et al.*[12] reported nine (2 per cent) device failure complications, whereas Lima Junior *et al.*[13] reported three cases (1 per cent).

In this study, one patient had skin flap failure and another had implant body migration under the scalp. These two patients underwent revision surgery without device extraction. One patient had severe infection that required hospitalisation and intravenous antibiotic treatment. One patient had extrusion of the implant body (internal receiver–transmitter) through the scalp following head trauma. Management of skin flap complications seems difficult in cochlear implantation cases. Flap complications may appear secondary to inflammatory and/or infectious processes around the implant body, and staged surgical interventions along with broad-spectrum antibiotics may be required for appropriate management. Major skin flap complications have been reported to range between 1.1 per cent and 8.2 per cent in the literature.[20]

Two patients had chronic otitis media with tympanic membrane perforation, and underwent tympanoplasty. One patient had chronic otitis media with cholesteatoma after cochlear implantation, and the implant was extruded. Cochlear implantation for patients with chronic otitis media with or without cholesteatoma can be performed in a staged manner following tympanoplasty. We prefer to perform either closed tympanoplasty or subtotal petrosectomy and cul de sac closure, with follow up for at least six months to monitor for any residual or recurrent disease. We perform cochlear implantation if the patient is disease-free. A similar staged approach is also recommended for patients who develop chronic otitis media with or without cholesteatoma following cochlear implantation.[21]

In this study, two patients developed problems with the magnetic attachment of the external part of the cochlear implant. Flap reduction surgery was performed in these two patients to manage this problem.

A 'gusher' is the sudden exit of high-flow CSF. 'Oozing' is the intermittent and low-flow exit of CSF that ceases after a few minutes. A CSF gusher usually lasts for 10–20 minutes and is generally treated conservatively. In this study, only one patient needed revision surgery for a CSF gusher that could not be managed conservatively. In this study, the incidence of a CSF gusher or oozing was 4 per cent, corresponding with the incidence of CSF gushers reported in a previous report, in the range of 1–5 per cent.[22]

Five patients (1 per cent) had problems with electrode migration. Terry *et al.*[19] reported a similar rate of 0.7 per cent. These five patients underwent revision surgery. In order to avoid this complication, it may be necessary to secure the device with stitches, create a bed for the implant body within the bone, or create a smaller or tighter subperiosteal pocket.

This study has some limitations, including its retrospective design and relatively small cohort of patients. In addition, the analysis of functional results was limited.

- The actual complication rate of cochlear implantation is relatively low
- Cochlear implantation should be considered a safe procedure
- Cochlear implantation is being performed with increasing frequency and has good success

Cochlear implantation is being performed with increasing frequency, and it is successful in terms of improving patients' hearing levels and quality of life. Although the procedure has potential for significant intra- and post-operative complications, the complication rate is relatively low. Therefore, cochlear implantation can be considered a safe procedure.

Competing interests. None declared

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