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Complications of cochlear implants: a MAUDE database study

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Abstract

Objective. A retrospective cross-sectional analysis was conducted of the US Food and Drug Administration's MAUDE (Manufacturer and User Facility Device Experience) database, to evaluate the complication profile of cochlear implantation according to manufacturer.

Methods. A review of the MAUDE database was conducted from 1 January 2010 to 31 December 2020. Complications, including infection, extrusion, facial nerve stimulation, meningitis and cerebrospinal fluid leak, were identified using key word searches. The categorised data were analysed using a chi-square test to determine a difference in global complication incidence between three major cochlear implant manufacturers: manufacturer A (Cochlear Limited), manufacturer B (Med-El) and manufacturer C (Advanced Bionics).

Results. A total of 31 857 adverse events were analysed. Implants of manufacturer C were associated with a statistically higher rate of infection (0.97 per cent), cerebrospinal fluid leak (0.07 per cent), extrusion (0.44 per cent) and facial nerve stimulation (0.11 per cent). Implants of manufacturer B were associated with a statistically higher rate of meningitis (0.07 per cent).

Conclusion. Consideration of patient risk factors along with cochlear implant manufacturers can heighten awareness of cochlear implant complications pre-operatively, intra-operatively and post-operatively.

Introduction

The World Health Organization reports a rise in the rate of hearing loss, with 466 million people living with disabling hearing loss worldwide.[1] The cochlear implant is a cornerstone option of hearing loss management in patients whose management needs are greater than can be met by traditional hearing aids.[2,3] With over 500 000 recipients of cochlear implant devices to date, an analysis of the complications will further quantify the risks of cochlear implant surgery. Understanding the potential risks of cochlear implants is important for patient informed consent and for surgeons to appropriately educate patients about post-operative complications.[4]

The US Food and Drug Administration's MAUDE (Manufacturer and User Facility Device Experience) database mandates the reporting of complications that lead to 'death and serious injury' by manufacturers, importers and device user facilities.[5] Recent analyses of the MAUDE database, conducted in 2005 and 2013, revealed trends of cochlear implant complications. The 2005 study revealed spontaneous device failure as the largest contributor to device failure.[6] The 2013 study reported a statistically significant increase in 'idiopathic performance decrement' and 'idiopathic loss of lock' from 2000 to 2010. This article categorised cochlear implant complications into device malfunction (software or hardware) and patient injury (infection, meningitis, cerebrospinal fluid (CSF) leaks or facial nerve stimulation).[7]

Our study aimed to analyse the hardware-related complications of cochlear implants in the past decade. We will do this by reporting the rate of infection, extrusion, facial nerve stimulation, meningitis and CSF leak, from 2010 to 2020, as conveyed to the MAUDE database. We will also investigate the three main manufacturers of cochlear implants and determine any variations between the companies.

Materials and methods

An institutional review board exempt status for the study was obtained from Mercy Health (Youngstown, Ohio, USA).

MAUDE database compilation

We accessed adverse event reports from the MAUDE database for all devices manufactured by manufacturer A (Cochlear Limited, Sydney, Australia), manufacturer B (Med-El, Innsbruck, Austria) and manufacturer C (Advanced Bionics, Valencia, California, USA), with report dates between 1 January 2010 and 30 December 2020.

Main Article

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

Some of the data were presented at the American Academy of Otolaryngology–Head and Neck Surgery Foundation Annual Meeting, 3–6 October 2021, Los Angeles, California, USA.

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From these records, we included cochlear implant reports and excluded those related to bone conduction implants.

Key word search

Records were filtered by key words to search for the presence of certain variables. Specific key word searches were: 'extru' for extrusions, 'meningitis' for meningitis, 'infection' for infection, 'facial nerve stimul' for facial nerve stimulation and 'CSF leak' for CSF leaks. Key word searches were controlled for false negatives and false positives, such as 'nerve stimulation not reported' or 'no infection present'. We randomly evaluated 10 per cent of reports following the key word search to reaffirm event classifications, and calculated an acceptable error rate of less than 0.1 per cent in our search process.

Total device sample size determination

The Cochlear Limited Annual Report from 2020 was used to determine the total number of cochlear devices implanted by manufacturer A from 2010 to 2020. This number (312 011) was compared with publicly available global market share data from multiple sources in order to extrapolate estimates of the total number of devices implanted between 2010 and 2020.[8,9] Specifically, the global market share of manufacturer A, B, and C was estimated to be 55, 20 and 20 per cent, respectively. The total number of implanted devices was accordingly extrapolated to be 312 011, 113 459 and 113 459 for manufacturers A, B and C, respectively. The number of complications from the key word search (described above) was divided by each respective data point to determine the estimated global rate of each complication per manufacturer.

Statistical methods

Records were evaluated with chi-square tests to determine whether a difference in complication rate for each variable existed between the three manufacturers. A chi-square test was also run comparing the rate of meningitis to the rate of CSF leak, regardless of manufacturer. For all analyses, a Bonferroni corrected p-value of less than 0.008 was used to determine significance.

Results

General findings

A total of 32 785 adverse event reports were obtained for analysis. After selecting only cochlear implant related reports, 31 857 reports were available for analysis. Of these reports, 15 953 (50.0 per cent) concerned manufacturer A devices, 8266 (25.9 per cent) related to manufacturer B devices and 7683 (24.1 per cent) involved manufacturer C devices. In our 10-year study period, a total of 538 929 cochlear implants have been sold globally based on market share extrapolation. Further, 312 011 manufacturer A devices were estimated to have been implanted in the same period as 113 459 devices for manufacturers B and C each. The total complication rate for cochlear implantation in the past 10 years is 5.91 per cent. Overall, 3836 cochlear implant recipients (0.71 per cent) experienced infection, 1819 (0.34 per cent) extrusion, 421 (0.08 per cent) facial nerve stimulation, 248 (0.05 per cent) meningitis and 169 (0.03 per cent) experienced CSF leak (Table 1). There was no demographic information (e.g. age, sex, race) provided by the database for analysis.

Table 1. Classification of adverse events

Adverse event	Reports (n (%))
Infection	3836 (0.71)
Extrusion	1819 (0.34)
Facial nerve stimulation	421 (0.08)
Meningitis	248 (0.05)
CSF leak	169 (0.03)

CSF = cerebrospinal fluid

Infection by manufacturer

Manufacturer C had the statistically highest rate of reported infections ($p < 0.008$) of 0.97 per cent ($n = 1097$), followed by manufacturer A with 0.79 per cent ($n = 2472$) and manufacturer B with 0.24 per cent ($n = 267$) (Fig. 1).

Extrusion by manufacturer

Manufacturer C had the statistically highest rate of device or electrode extrusion ($p < 0.008$) of 0.44 per cent ($n = 500$), followed by manufacturer A with 0.37 per cent ($n = 1165$) and manufacturer B with 0.13 per cent ($n = 152$) (Fig. 1).

Facial nerve stimulation by manufacturer

Manufacturer C had the statistically highest rate of facial nerve stimulation ($p < 0.008$) of 0.11 per cent ($n = 123$), followed by manufacturer A with 0.07 per cent ($n = 230$) and manufacturer B with 0.06 per cent ($n = 69$) (Fig. 1).

Meningitis by manufacturer

Manufacturer B had the statistically highest rate of reported meningitis ($p < 0.008$) of 0.07 per cent ($n = 83$), followed by manufacturer A with 0.04 per cent ($n = 120$) and manufacturer C with 0.04 per cent ($n = 45$) (Fig. 1).

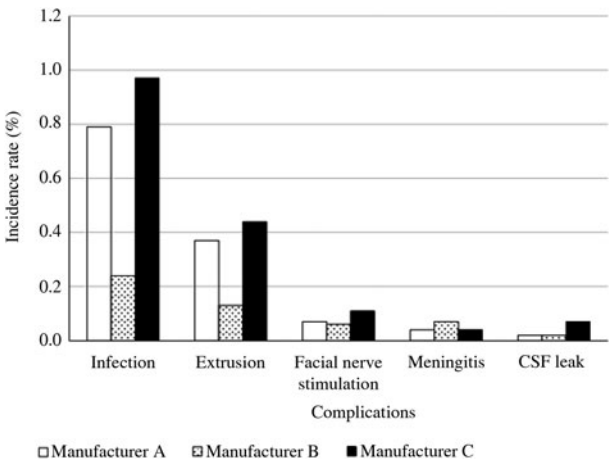

Figure 1. Incidence of complications by manufacturer. CSF = cerebrospinal fluid

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Cerebrospinal fluid leak by manufacturer

Manufacturer C had the statistically highest rate of reported CSF leaks ($p < 0.008$) of 0.07 per cent ($n = 84$), followed by manufacturer A with 0.02 per cent ($n = 61$) and manufacturer B with 0.02 per cent ($n = 24$) (Fig. 1).

Cerebrospinal fluid leak versus meningitis

It was shown that those patients with a CSF leak were significantly ($p < 0.008$) more likely to have meningitis than those without a CSF leak, with 35.50 per cent ($n = 60$) of patients with CSF leaks having meningitis (Fig. 2a) versus 0.59 per cent ($n = 188$) of patients without CSF leak having meningitis (Fig. 2b).

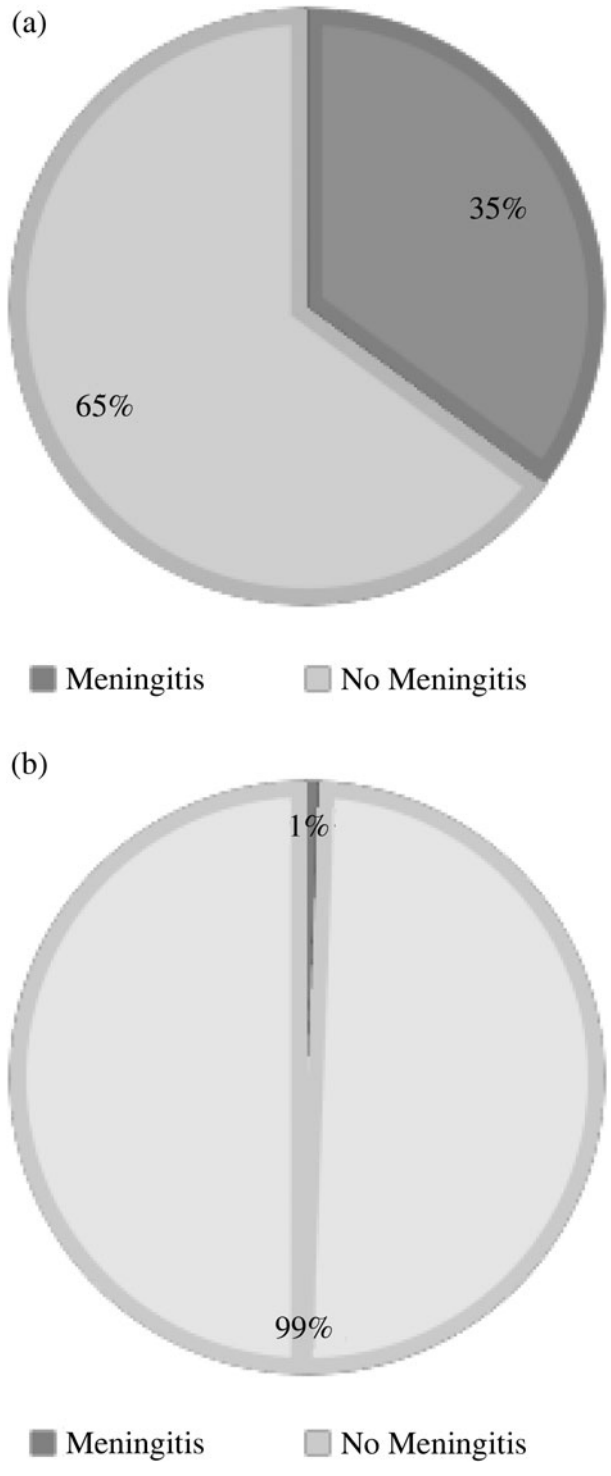

Figure 2. Patients with (a) and without (b) cerebrospinal fluid leaks.

Discussion

Our data demonstrated that infection (0.71 per cent) and extrusion (0.34 per cent) were the two most reported complications, in comparison to facial nerve stimulation (0.08 per cent), meningitis (0.05 per cent) and CSF leak (0.03 per cent). Our results also revealed the distribution of complications between manufacturers. Manufacturer C had a statistically greater rate of infection, extrusion, facial nerve stimulation and CSF leaks, and manufacturer B had a statistically greater rate of meningitis. These findings may indicate over-reporting of complications of manufacturer C's cochlear implants, but, nonetheless, the data are clinically relevant for determining complications associated with the products of each device manufacturer.

Infection is a commonly reported complication of cochlear implants. The infection rate in cochlear implant recipients ranges from 1.4 per cent to 8.2 per cent, based on the most recent literature.[10,11] Common infections in cochlear implant recipients include skin infections, labyrinthitis, acute otitis media and mastoiditis.[12] Biofilm formation is a predisposing factor for antibiotic-resistant infection in cochlear implant recipients.[13–15] Some risk factors for post-operative infection include a history of chronic ear infections[16] and younger age.[17,18] Manufacturer C had the statistically highest rate of infection based on our data. If cochlear implantation is undertaken, Vijendren *et al.* (2019) suggest the use of intra-operative prophylactic antibiotics, to prevent infections.[19] However, there is no uniform protocol for preventing infection. The infection rate in our study is lower than previously reported infection rates.

Implant extrusion is one of the most common complications of cochlear implants.[20] The rate of extrusion may be under-recognised.[21] There are multiple predisposing factors, including cochlear ossification,[22] adhesions, trauma, infection,[21] and growth of head circumference in children.[23] In the MAUDE database, extrusion can be secondary to electrode migration or cutaneous extrusion of the stimulator or receiver (these were not differentiated). Gatto *et al.* (2021) postulated that cochlear implant extrusion can be prevented by a surgical technique to fix the receiver/stimulator.[24] Vaid *et al.* (2011) published data suggesting that perimodiolar electrodes have a lower rate of extrusion.[21] Further study of the cochlear implants could explain a relationship between electrode type and extrusion rate.

Aberrant facial nerve stimulation is a known complication of cochlear implants. A retrospective chart review reported that 14 per cent of patients experienced facial nerve stimulation following cochlear implantation of devices from manufacturers A, B and C.[25] The most stimulated segment of the facial nerve is the labyrinthine segment.[25] Some risk factors for facial nerve stimulation cited in the literature include otosclerosis, and lateral wall electrodes as opposed to perimodiolar electrodes.[25,26] Our study demonstrated an overall rate of reported facial nerve stimulation of 0.08 per cent, considerably lower than previously reported in the literature.

Cerebrospinal fluid leaks and meningitis are less commonly reported complications of cochlear implants. However, they lead to elevated levels of morbidity and mortality.[27] A retrospective chart review of 523 cochlear implant recipients found that 2.87 per cent of patients had a CSF leak, 80 per cent of whom had inner-ear malformations.[28] Other retrospective chart reviews have cited inner-ear malformations as a risk factor for CSF leaks

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in paediatric and adult populations.[29,30] Other anatomical variations, such as stapes footplate defects[31] and air–bone gaps[32] predisposed cochlear implant recipients to CSF leaks. Obesity[33] and X-linked deafness[34] have also been cited as risk factors for CSF leaks. Although meningitis is a rare complication, there is a greater rate of meningitis in cochlear implant recipients compared to their age-matched cohort of the general population.[27] Certain factors increase the risk of meningitis. Stapes footplate defects[31] and CSF leaks[35] are risk factors in the development of meningitis in cochlear implant recipients. Our study results suggest that CSF leaks present with meningitis with greater frequency than meningitis without CSF leaks. Our study also demonstrated low rates for both meningitis, at 0.05 per cent, and CSF leaks, at 0.03 per cent. The meningitis risk can be reduced with a non-traumatic design, an adequate fibrous seal around the cochleostomy site, and proper surgical technique.[27,36]

- Cochlear implantation is an option for hearing loss management; over 500 000 devices were implanted over the past 10 years
- There have been no MAUDE database studies after 2013 examining cochlear implant complications; this study analysed complications in the past decade
- The study reported rates of infection, extrusion, facial nerve stimulation, meningitis and cerebrospinal fluid (CSF) leaks for 2010–2020, as reported in the MAUDE database
- It investigated the three main cochlear implant manufacturers and any variations in reported complication rates
- Manufacturer C had higher rates of infection, CSF leak, extrusion and facial nerve stimulation; manufacturer B had a higher rate of meningitis
- Consideration of patient risk factors and cochlear implant manufacturers can heighten awareness of cochlear implant complications

Limitations

Our study used global market share data to extrapolate the total number of implanted devices sold by each manufacturer. However, variation between manufacturer reporting limited reliability. Furthermore, we did not consider implants manufactured by smaller companies including Neurelec (Vallauris, France) and Oticon (Copenhagen, Denmark).

Another limitation is that MAUDE database reports are overwhelmingly US-based, suggesting our manufacturer-specific complication rates are not an accurate global representation. Our attempts to reach out to manufacturers for data were met with resistance. We hope that this study will encourage manufacturers to share more market data in the future in order to encourage transparent post-market surveillance.

Finally, some details are missing from the MAUDE database, including vaccination status, surgical technique, patient demographic information, duration of implantation, and the presence of any underlying anatomical abnormalities. Additionally, the MAUDE database relies on a combination of mandatory and voluntary reporters, such as healthcare professionals, patients and consumers, which can confound reliability. Nonetheless, the MAUDE database remains one of the only databases for the analysis of device-related complications, and has been employed for previous analyses within and outside the field of otolaryngology.[37–42]

Conclusion

Our study compared cochlear implant complications between the three major manufacturers over a 10-year period utilising the MAUDE database. Our research does not show a clearly superior manufacturer in cochlear implantation. Further research with more co-operation from manufacturers is needed to investigate the mechanisms behind, and true global incidence of, these complications. We encourage manufacturers of cochlear implants to work more willingly with researchers in the future in order to conduct this type of analysis. Taken together, alongside careful analysis of patient history and anatomy, this study can aid providers in anticipating complications of cochlear implants, while laying the groundwork for future post-market cochlear implant studies.

Competing interests. None declared.

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