ORIGINAL ARTICLE

Cochlear Implant Complications

Utility of Federal Database in Systematic Analysis

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Objectives: To explore the suitability of the Manufacturer User Facility and Distributor Experience (MAUDE) database (which is maintained by the Food and Drug Administration and has a mandatory reporting requirement) for systemic analysis of cochlear implant complications and treatments and, in so doing, analyze trends in cochlear implant complications for 2 periods, 2002 and pre-1998.

Data Sources: All events from 2002 and from before 1998 were considered. Events and action taken were categorized and tabulated.

Data Synthesis: Because there was no null hypothesis, statistical analysis (χ^2) was only used in comparing the 2 time frames.

Conclusions: Structural limitations of the database, in addition to disparate reporting quality, made systematic analysis difficult. It was noted that spontaneous device failure accounted for the greatest single number of adverse events for both 2002 and the pre-1998 period (267/654 [41%] and 74/129 [57%], respectively), confirming earlier studies. A statistically significant decrease in spontaneous device failure and a significant increase in infections from the pre-1998 period to 2002 was observed. Flap problems ranging from extrusion to infection that required explantation were less frequently reimplanted than other problems requiring explantation, such as device failure or trauma. We considered new directions, including close collaboration with the new MedSun reporting system and conclude that while a valuable resource for narrative data, the current structure of the MAUDE database is only modestly useful for analyzing trends in complications and cannot answer several crucial questions, including device type comparisons. We suggest changing the current report format to include patient age, duration of implant, presence of anatomical abnormalities, and details on spontaneous device failures.

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COCHLEAR IMPLANTS remain a popular and effective therapy for patients with sensorineural hearing loss in whom traditional hearing aids do not provide satisfactory results. Although very successful, cochlear implants remain expensive and require an extensive program of accompanying therapy to be most effective. Given this commitment, the nature and rate of complications is a topic of considerable interest. Implant patients or their parents rightly have numerous questions such as the following:

- How long will the implant last?
- What is the chance the implant will fail?
- What is the chance of an infection or other serious complication?
- Which manufacturer or model has the lowest occurrence of complications?
- If better implants become available, is it possible to "upgrade"?

Manufacturer-supplied literature on device complications addresses many of these questions,[1] but patients and clinicians (who also frequently receive personal communications from companies reviewing

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safety data) often look to independent, third-party data sets for additional confirmation of these results. Furthermore, information provided by companies naturally deals primarily with that company's devices, making comparisons across brands difficult. A modest body of peer-reviewed literature does exist on the epidemiology of cochlear implant complications, with the first large-scale effort in

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1988 by Cohen et al,[2] which found an overall complication rate (excluding electronic device failure) of 11.8% in a sample of 459 operations. The study by Cohen et al[2] was limited to the Nucleus multichannel device available in 1988 and prior. Subsequent studies have reflected the experience of a single center[3] or have been analyses of manufacturer data sources; most of these studies have reported complication rates from 1.8% to 4.9%.[4-7] Of complications requiring explantation and/or reimplantation, electronic device failure has consistently emerged as the most common and tends to be especially common in the pediatric population, with one 2001 study reporting device failure for 17 of its 19 pediatric reimplants.[8] Differing flap techniques (C-shaped vs postauricular) give rise to the question of whether a specific flap carries a greater or lesser risk of complications.

An ongoing debate in the literature revolves around the efficacy of reimplantation surgery. As technology improves, it is not unreasonable to believe that many children who currently have implants may wish to eventually upgrade. Thus it is furthermore necessary to establish that such surgical procedures are safe and effective. Miyamoto et al[9] demonstrated that, on average, the electrode insertion length was shorter on reimplantation than on initial implantation, citing concerns about ossification and scar formation. Subsequent studies by Balkany et al[10] and Parisier et al[11] have failed to corroborate these results and in fact have shown maintenance or improvement in objective hearing measures for most patients.

While these studies have significantly advanced our understanding of the incidence and prevalence of cochlear implant complications, an underutilized resource is the Manufacturer User Facility and Distributor Experience (MAUDE) database, which is maintained by the Food and Drug Administration (FDA) and described on their Web site.[12] Established in 1996 to replace the previous Medical Device Reporting (MDR) database, MAUDE is a mandatory report database of major and minor complications for a wide variety of medical devices, including cochlear implants. The data consist of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. By the rules of the database, health care facilities are required to report complications believed to arise from implantable medical devices within 10 days of occurrence. Manufacturers are similarly required to report within 30 days of becoming aware of the event or malfunction. Of note, practitioners in private offices are not considered to be in the class of health care facilities required to report. However, experience suggests that most implants occur in the context of a hospital-based, comprehensive implant program. Adverse events occurring outside the United States must also be reported if the device is approved for use in the United States. These events are assigned a unique FDA event number, and the electronic form contains information such as the date, the device type, a brief narrative describing the nature of the complication (including any relevant laboratory or clinical data) and, in many cases, a description of the treatment plan. We hypothesize that given the size and scope of this database, as well as its mandatory reporting requirement, it will allow for an accurate tabulation and analysis of cochlear implant complications worldwide.

The objectives of the present study were to explore the suitability of this database for systemic analysis of cochlear implant complications and treatments and, in so doing, analyze trends in cochlear implant complications for 2 periods, 2002 and pre-1998. We chose these 2 distinct periods, as opposed to a continual series, because we believed that the quality of the reports could change as reporting agents and end users grew more accustomed to the database and began to demand more completeness and flexibility from it. The value of such a worldwide storehouse of data is clear, yet any new reporting requirement will likely have a lag time in which the initial reports are spotty and less helpful than those provided to a large, well-established database.

As mentioned, previous studies reflected the experience of a single center or an analysis of manufacturer data. We believe that the MAUDE database afforded a unique opportunity to use worldwide data collected and organized by an impartial source, with a mandatory reporting requirement. Although the database does not require the reporting of malfunctions that do not threaten the life or health of the patient, it does require the reporting of malfunctions that compromise the essential function on the implant, so in this case nearly all significant cochlear implant malfunctions would be reported.

METHODS

DATA COLLECTION

The MAUDE database was accessed via the World Wide Web.[13] Search terms for adverse event reports included "cochlear implant" and device code "MCM." The search was limited to those reported from January 1, 2002, to December 31, 2002, and all those reported before December 31, 1997. These 2 periods were chosen for the following reasons. Because the manufacturers were required to report adverse events beginning in August 1996, the first full year of data using the reporting mandates that we have at present would be at the end of 1997. Although each of the 3 manufacturers has made improvements at some point yearly after 1997, it was believed that 5 years would allow for trends in outcome variations secondary to evolution of surgical technique (ie, incision modifications) to affect most surgeons.

For some reports, no report date was specified; in those cases the date the report was received by the FDA was used instead. All reports falling within the specified date range were included. Each report was summarized into a record, consisting of the report date, the FDA event key, the device type and manufacturer, a brief description of the event, and the described treatment course.

DATA ANALYSIS

Due to the narrative style of the last 2 categories, it was necessary to interpret and categorize the events and treatments; because the database was designed to be descriptive and inclusive, it was impossible to create a priori categories. The events were described and categorized as in **Table 1**. Seven categories were developed on the basis of the narrative descriptions and events that were believed to be clinically similar. Nonverifiable patient complaints encompassed a diverse array of complaints, including "strange sounds," vertigo, "unpleasant sensations," and other complaints that, while disturbing to the

Table 1. Event Categories and Relevant Examples

Categorized Event	Examples	2002, No. (%)	Pre-1998, No. (%)
Flap problem	Flap necrosis, flap infection, flap dehiscence, device extrusion	82 (12.5)	20 (15.5)
Nonverifiable patient complaint	Strange sound, dizziness, unpleasant sensation	64 (9.8)	7 (5.4)
Infection	Meningitis, otitis, infection, site not specified	109 (16.6)	3 (2.3)*
Surgical technical complication	Perilymph fistula, misplaced electrode	32 (4.9)	4 (3.1)
Migration	Electrode or receiver migration	37 (5.6)	9 (7.0)
Confirmed spontaneous device malfunction	Broken hermetic seal, electrostatic discharge	267 (40.8)	74 (57.4)*
Trauma-induced device malfunction	Head injury	63 (9.6)	12 (9.3)
Uncharacterizable		7 (1.1)	2 (1.5)

*Significant difference ($P<.05$).

patient, could not be verified through objective measures. Flap problem was inclusive of flap infection; infection was inclusive of meningitis, otitis, and those cases described as "infection" with no further specification. Surgical technical complication was limited to those cases in which the primary clinical problem was directly related to the surgery and not those related to postoperative healing (such as flap problems), including misplaced electrode, perilymph fistulae, and others noted in Table 1. Because electrode migration most commonly reflects an underlying neoossification, it was categorized separately. Seven cases did not coherently describe the adverse event and described either a clear or "pending" (vide infra) treatment plan. For these points the treatment data were kept and the event ignored, hence the cross-tabulation data reflect the total events, not the total treatments.

The treatments instituted as a result of the complication were similarly categorized, as in **Table 2**. The surgery category included those surgical interventions that were not an explantation or reimplantation. Medical treatment included those cases in which no surgery was performed; most commonly, this category described antibiotic treatment for infections. In numerous cases, no definitive treatment was described—only a future treatment plan with no explicit mention that that plan had been carried out. Such records were categorized as "pending." Every effort was made to avoid interpreting or imputing information, though as mentioned in some cases this was impossible.

The data were grouped into 2 time frames, 2002 and pre-1998. Although the pre-1998 period included data from as early as 1993, given the small number of entries and nature of reported complications we do not expect any significant year-to-year variability, so we do not expect this to affect our data. Within each time frame, no statistical analysis was necessary because there was no null hypothesis; we sought only the overall frequencies of events within each time frame. The data were tabulated using SPSS software (SPSS for Windows, Release 11.5.0; SPSS Inc, Chicago, Ill). χ^2 Analysis was used to compare the 2 data groups for each event between the 2 time frames.

RESULTS

The simple frequencies and percentages are reported in Tables 1 and 2. It is important to note that these events are reported regardless of implant duration, so while some occurred immediately after implantation, some occurred years after implantation. If data on total implant numbers were available, the time from implantation to adverse event would obviously have a significant impact on differentiating incidence and prevalence. For 2002 and the period before 1998, 661 and 131 cases, respectively, were totaled. In 7 cases in 2002 and 2 cases in the pre-1998 period, the description of the adverse event could not be accurately described based on the narrative data provided. Consistent with prior studies, mechanical failure was clearly the most common serious complication and the most common cause for explantation and/or reimplantation, accounting for 267 (40.8%) of cases described in 2002 and 74 (57.4%) in the pre-1998 period. There is no clear second most common cause, although infection predominates slightly in 2002. Trauma, surgical complications, nonverifiable patient complaints, and flap problems appear to be about equally common. As noted in Table 1, a statistically significant difference ($P<.05$) was noted in 2 adverse events, infection and confirmed device malfunction. Infection was significantly more common in 2002 and device malfunction was more common in the pre-1998 period. No other significant differences in events were noted.

Table 2. Treatment Categories and Frequencies

Treatment	2002, No. (%)	Pre-1998, No. (%)
Explantation	195 (29.5)	22 (16.8)
Explantation/reimplantation	162 (24.5)	77 (58.8)
Medical treatment	61 (9.2)	1 (0.8)
None	3 (0.5)	1 (0.8)
Pending	185 (27.9)	18 (13.7)
Surgery	53 (8.2)	12 (9.2)
Total	**659**	**131**

Among actions taken, at first pass it appeared that reimplantation was more common in the pre-1998 period, but it is important to note that the "pending" category in 2002 was large and accounted for nearly 30% of the actions taken. Therefore, it cannot be reliably stated that reimplantation was more common in the pre-1998 period. Furthermore, the high incidence of "pending" data makes reliable statistical analysis on these action data impossible. However, it is clear that for most of the adverse events described, surgical intervention, most commonly explantation or reimplantation, was the most common treatment. In fact, infection was virtually the only adverse event treated medically, without surgery. The cross-tabulation tables for each year (**Table 3** and **Table 4**) provide an interesting snapshot of complications and their most common treatments, but none rise to the level of statistical significance.

Table 3. Cross-tabulation, 2002 Data*

Treatment	Flap Problem	Patient Complaint	Infection	Surgical Technical	Migration	Spontaneous Device Malfunction	Trauma-Induced	Total
Explantation	43 (22.3) (52.4)	23 (11.9) (35.9)	26 (13.0) (23.8)	18 (9.3) (56.3)	16 (8.3) (43.2)	58 (30.1) (21.7)	10 (5.2) (15.9)	**194** . . . (29.5)
Explantation/ reimplantation	12 (7.5) (14.6)	14 (8.8) (21.9)	10 (6.3) (9.2)	8 (5.0) (25.0)	2 (1.3) (5.4)	87 (54.4) (32.6)	27 (16.9) (42.9)	**160** . . . (24.5)
Medical treatment	3 (4.9) (3.7)	0	58 (95.1) (53.2)	0	0	0	0	**61** . . . (9.3)
Surgery	17 (34.0) (20.7)	12 (24.0) (18.8)	3 (6.0) (2.8)	3 (6.0) (9.3)	14 (28.0) (37.8)	1 (2.0) (0.4)	0 0	**50** . . . (7.8)
Pending	7 (3.8) (8.5)	15 (8.1) (23.4)	11 (5.9) (10.1)	2 (1.1) (6.3)	5 (2.7) (13.5)	120 (64.9) (44.9)	25 (13.5) (39.7)	**185** . . . (28.3)
None	0	0	1 (25.0) (0.9)	1 (25.0) (3.1)	0	1 (25.0) (0.4)	1 (25.0) (1.6)	**4** . . . (0.7)
Total	**82** (12.5)	**64** (9.8)	**109** (16.7)	**32** (4.9)	**37** (5.7)	**267** (40.8)	**63** (9.6)	**654**

*Data are given as number (percentage [row%, adjacent; column%, underneath]). The totals are less than in Tables 1 and 2 because in some instances the event could not be clearly identified (see text).

Table 4. Cross-tabulation, Pre-1998 Data*

Treatment	Flap Problem	Patient Complaint	Infection	Surgical Technical	Migration	Spontaneous Device Malfunction	Trauma-Induced	Total
Explantation	6 (28.6) (30.0)	1 (4.8) (14.3)	2 (9.5) (66.7)	0	3 (14.3) (33.3)	5 (23.8) (6.8)	4 (19.0) (33.3)	**21** . . . (16.3)
Explantation/ reimplantation	8 (10.4) (40.0)	5 (6.5) (71.4)	1 (1.3) (33.3)	3 (3.9) (75.0)	1 (1.3) (11.1)	51 (66.2) (68.9)	8 (10.4) (66.7)	**77** . . . (59.7)
Medical treatment	1 (100.0) (5.0)	0	0	0	0	0	0	**1** . . . (0.8)
Surgery	5 (45.5) (20.0)	0	0	1 (9.0) (25.0)	5 (45.5) (66.6)	0	0	**11** . . . (8.5)
Pending	0	0	0	0	0	18 (100.0) (24.3)	0	**18** . . . (14.0)
None	0	1 (100.0) (14.3)	0	0	0	0	0	**1** . . . (0.8)
Total	**20** (15.5)	**7** (5.4)	**3** (2.3)	**4** (3.1)	**9** (7.0)	**74** (54.7)	**12** (9.3)	**129**

*Data are given as number (percentage [row%, adjacent; column%, underneath]). The totals are less than in Tables 1 and 2 because in some instances the event could not be clearly identified (see text).

Although the initial thought was to use the database to analyze differences between specific devices and manufacturers, this was ultimately deemed impractical based on limitations of the database. We were furthermore unable to get accurate counts of the number of active implants in the field for each manufacturer (although the Cochlear Web site[14] gives their total recipient number as 51 768 as of January 15, 2004). As mentioned, there was significant variability in the quality of the narratives, and it was impossible to parse out which nontechnical complications could be attributed to the device or to the surgeon, support staff, or user. As such, the analysis would lack validity.

COMMENT

The purpose of the present study was to explore the utility of the MAUDE database for analyzing trends in cochlear implant complications. Confirming other studies, we found device failure to be the most commonly reported complication. We also found a significant decrease in device malfunction from the pre-1998 period to 2002, possibly reflecting increasing quality control and reliability on the part of manufacturers. Each manufacturer has described improvements in the technology of their implants. The sharp increase in infection is more difficult to explain. It is possible that, early in the history of this database, there was a relative underreporting of complications that may have been perceived as minor. In addition, such an underreporting of infection could affect the significance of the malfunction data, since an increase in infections would decrease the relative percentage of malfunctions as a total of reported complications, possibly bringing it more in line with the 2002 malfunction numbers. Furthermore, we acknowledge that the creation of 7 categories also determines the degrees of freedom for the

χ^2 analysis, so a different categorization may yield different levels of statistical significance. Given the strength of the significance, it seems unlikely that the significance is due entirely to the chosen categorization system.

The MAUDE database offers a unique opportunity in that it contains information from both the manufacturer and the health care providers about devices from all manufacturers and from a variety of medical centers. As a mandatory report database, it could potentially generate the most accurate catalogue of cochlear implant complications worldwide. However, we have demonstrated that although the MAUDE database contains a great deal of useful information, it lacks sufficient categorization to allow for a clear systematic analysis.

In 2002, the FDA began a partnership with the CODA research group (CODA Inc, Silver Spring, Md) to dramatically alter the way in which medical device complication data were gathered and analyzed. This partnership, known as MedSun for Medical Device Surveillance Network, entrusts CODA with the opportunity to organize and analyze the MAUDE data in new ways and present it to the community of researchers, users, and clinicians in novel formats. MedSun effectively became the new user-friendly front end of the MAUDE database. Cited benefits of this new method include ease of use and, perhaps more important, the creation of a research community with enough ongoing analysis and discussion that the opportunity to participate is itself a positive incentive to increase the quantity and quality of reporting. The ongoing commentary could lead to prospective restructuring of future data.

This is a central point because one of the main weaknesses of the database, and hence our study, is that owing to the nature of the data it was necessary to develop categories of complication and treatment after tabulation. Insufficient demographic data existed to form a coherent picture of the patient population. Information such as patient age, date of implantation (an existing category in the MedSun report form), type of surgical flap used, number of previous implantations, preexisting cochlear or inner ear malformation, and relative experience of the center (both in surgical and ancillary expertise) would all have been invaluable in analyzing the data. We also found that, in numerous cases, the narrative description of cases was incomplete in that it did not describe a treatment plan, did not elaborate on the nature of the problem, or did not specify if any testing was performed by the manufacturer to delineate the exact problem. These differences in the quality of the reports made it impractical to compare different manufacturers and models. In addition, there is a wealth of information that would improve such an analysis without compromising patient or health care provider confidentiality.

Before discussing the nature of that additional information, it is important to concede that the standardized form 3500A used by the MAUDE database is not used exclusively for cochlear implants, nor is MedSun's standard data entry form, and therefore any changes made must preserve the suitability of the form for other devices, as well as allow for continued interdevice comparisons on the basis of a more generalized form. We believe one feasible solution to this problem is to leave the basic form unchanged but add categories uniquely suited to cochlear implants. Such extra closed-end fields, easily created with the current Web-based reporting forms, would increase uniformity and prevent the omission of crucial information from a narrative entry and could be excluded when a more general perspective is needed. It should be noted that the more sophisticated reporting form used by MedSun would be especially amenable to such a change.

As it stands, reports to MAUDE come from health care providers, manufacturers, and distributors. At times, events may go unreported owing to miscommunication between the parties. Automatic reporting triggers related to existing reporting vehicles such as warranties or hospital infection control/quality assurance committees could be linked to MAUDE or MedSun to prevent events from slipping through the cracks. This would be a significant first step in improving data capture.

First, we propose the development of an a priori categorization of adverse events. We believe that the system used in the present article is suitable, though we would appreciate the input of our colleagues on the development of the most useful system. Although this would still entail interpretation on the part of the reporter, it would prevent a retrospective categorization affecting the statistical outcomes. This categorization will give greater insight into the relative proportions of complications. Furthermore, within the category of spontaneous device failure, we suggest subcategorizations related to specific parts or malfunctions, such as receiver housing, electrode array, loss of hermetic seal, short circuit in the electronics, and other specific components of the implant, so that manufacturers and health care providers will have the opportunity to compare individual products against each other.

Our second proposal is the development of an objective, closed-end entry area for which the following information is added: patient age, a notation of any underlying anatomical abnormality, duration of implant, if reimplantation was performed and if it was ipsilateral or contralateral, and how many previous implantations the patient has had. These categories will allow the assessment of pertinent risk factors and estimation of the useful life of the implant. These categories should not compromise patient confidentiality and may be especially important in light of the recent results of Reefhuis et al,[15] showing that abnormal cochlear or auditory canal anatomy is a significant risk factor for meningitis in cochlear implant patients. Some method of tracking a center's experience would also be invaluable, although it might be difficult to do so and preserve a center's confidentiality. Along these same lines, a system of "healthy checkups" for the implants that reported data to a central repository could yield data that, considered retrospectively when a device fails, give insight into risk factors for device failure.

Third, although we believe this would be difficult and perhaps impractical at present, some basic data on preoperative and postoperative audiograms and whether the deafness was prelingual or postlingual would be extremely useful. The sum of our new suggested categories are summarized in **Table 5**. The article by Reefhuis et al[15] brings to light an interesting point that we

Table 5. Proposed New Entry Fields for MAUDE Database

Category	Rationale
Device malfunction type*	More specific characterization of device failure
Patient age	Implant demographics, risk factor, establish separate pediatric population
Anatomical abnormalities	Risk factor
Duration of current implant	Calculate implant lifespan, calculate risk over implant lifespan
Ipsilateral or contralateral reimplantation	Implant demographics, feasibility of upgrade/reimplantation
No. of implantations	Feasibility of upgrade, likelihood of reimplantation success

Abbreviation: MAUDE, Manufacturer User Facility and Distributor Experience.
*Loss of seal, short circuit, electrode malfunction.

believe makes our suggested improvements imperative. Those authors had available to them a level of data (some from the Centers for Disease Control and Prevention) that is not generally available to those using the public MAUDE database; this disparity prevents other researchers from performing similar analyses. Given the importance of their findings, it is clear that government data of this quality should be widely available to allow many members of the research community the opportunity to explore important trends affecting patient safety. We believe that improving the database as we have proposed will increase the value of work done with this database and bring those findings to light in a more timely fashion.

In summary, we believe that the MAUDE database is a valuable resource and can be improved to allow for detailed analysis of complications and adverse events associated with cochlear implants. At present, however, we are aware of its structural limitations. Returning to the questions posed at the beginning of this article, we unfortunately found that the current database structure does not allow for accurate, comprehensive answers to any of the questions. Our analysis shows that spontaneous malfunction is the most commonly reported event (as similarly shown in other studies) and, encouragingly, that the percentage of such malfunctions has decreased as a total of reported complications from the pre-1998 period to 2002—a logical finding, given the technical improvements by manufacturers. Although we acknowledge its limitations, we believe that given the combination of mandatory reporting and the relative familiarity of centers with MAUDE at present, it remains the most logical starting point for a comprehensive, user-driven database. Beginning an entirely new system has its appeal but would require a significant amount of time to build a database and would suffer from lack of mandatory reporting. With the suggested improvements to the MAUDE database, it could become a powerful, sophisticated analytical tool for health care providers and patients alike. Used appropriately, it could provide crucial guidance in selecting an expensive but wonderfully life-enhancing therapy.

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