The Utility of the MAUDE Database for Osseointegrated Auditory Implants

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Abstract

Objective: To determine the utility of MAUDE in studying OAI related complications.

Study Design: Retrospective review of public data stored in MAUDE.

Methods: The MAUDE database was accessed on January 1, 2015 with all searches between January 1, 1996 and January 1, 2015. All reports were classified into 1 or more of six categories - implant, abutment, processor, skin, surgery, and other. Subcategories were generated to prevent overgeneralization. Other variables recorded included date of report, number of complications per report, manufacturer, and time from complication to report

Results: Over the study period there were 269 complications listed from 238 reports divided into the following categories: implant related (n=145), abutment related (n=16), processor related (n=13), skin and soft tissue related (n=79), surgery related (n=11), and other (n=5). No demographic data were available. There were no discernible trends from the data, and when compared to published literature, MAUDE data appears to under or misrepresent complications.

Conclusion: The MAUDE database is limited in its design, and given fairly disparate reporting quality may not be ideally suited for quantifying risks of OAIs. These findings suggest the necessity for a substantially improved central registry for otologic implants and highlight the need for further research to investigate the root causes of their associated complications.

Keywords: Osseointegrated; BAHA; Bone Anchored Hearing Aid; Complication; MAUDE; Database

Level of Evidence: 2b

Background

Osseointegrated Auditory Implants (OAI) are not without risks or complications. These adverse events can be either intraoperative or post-operative, and can be related to the surgical technique, the implant, the abutment, the processor, post-operate wound healing, or any combination therein. Reported complication rates are disparate. The incidence of skin reactions have been reported from 2.4%-38%, and loss of the implant (for any reason) from 1.6%-17.4%[3,4]. The presence of such a large discrepancy indicates the need for better and standardized tools for reporting of these complications.

The Manufacturer and User Friendly Device Experience[5] (MAUDE) database was established by the FDA to aid in the reporting and analysis of medical device-related complications. It is the largest openly searchable public database for device-related complications. Entries to MAUDE are broadly classified into two general categories - reports from mandatory reporters (manufacturers, importers, device using facilities) and reports from voluntary reporters (physicians and patients). Previous authors have used MAUDE to reveal trends in device complications with variable conclusions regarding its utility. This includes studies on the robot-assisted surgical systems, endometrial ablation devices, surgical lasers, automated external defibrillators, lariat devices for left atrial appendages, inferior vena cava (IVC) filters and cochlear implants (CI) among others[6-13]. Despite the increasing prevalence of OAI, it has never been studied for this patient population.

Methods

The MAUDE database was accessed on January 1, 2015 at the following website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfmaude/search.cfm. Because the earliest approval of the bone anchored hearing aid by the FDA was in 1996[14], all searches were between January 1, 1996 and January 1, 2015. The following search criterions were used: Manufacturer (Cochlear, Entific (which later became Cochlear), Oticon, Oticon Medical, Sophono) and Device (Bone anchored hearing aid, BAHA, Baha, Ponto, Alpha 2 MPO). Complications were classified into one of the six categories: 1) Implant-related, 2) Abutment-related, 3) Processor-related, 4) Skin-related, 5) Surgery-related, and 6) Other. All records were combined and duplicates removed. Subcategories were generated during review to prevent overgeneralization. The number of complications per report were recorded. Dates of complication (DOC) and dates of report (DOR) were also recorded. DOC and DOR that were within 12 months were considered to be within the same year.

Results

Data Summary

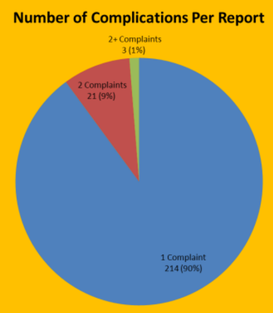

Figure 1

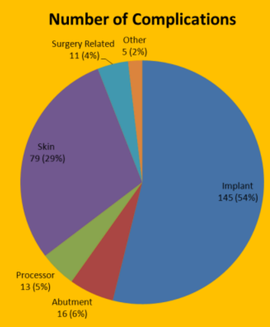

Figure 2

Complication Categories

Implant Related	Number of Reports
Pain	8
Implant Loss; Initial Failure to Osseointegrate	35
Implant Loss; Due to Trauma	21
Implant loss, due to revision surgery	3
Implant Loss; Due to Infection	7
Implant Loss; Etiology Unknown	71
Total	145

Abutment Related	Number of Reports
Pain	5
Abutment Loss/Removal	11
Total	16

Processor Related	Number of Reports
Broken Plastic	2
Broken Switch	1
Battery Leak	1
Processor Inoperable	2
Incorrect Programing	7
Total	13

Skin Related	Number of Reports
Infection	35
Allergic Reaction	1
Hypertrophic Scar	2
Seroma	1
Magnet Sore/Exposure	5
Skin Overgrowth	25
Wound Failure to Resolve	10
Total	79

Surgery Related	Number of Reports
Hematoma	3
Abscess, Post-operative	2
Subarachnoid Air	1
Misplacement of Device	2
Stripped Cover Screw	1
Surgical Maintenance of Device	2
Total	11

Other	Number of Reports
Dizziness	1
Finger Wrapped around Safety Line	1
Failure to Disconnect	1
Sterility Violation/Expiration	2
Total	5

Data Quality Concerns

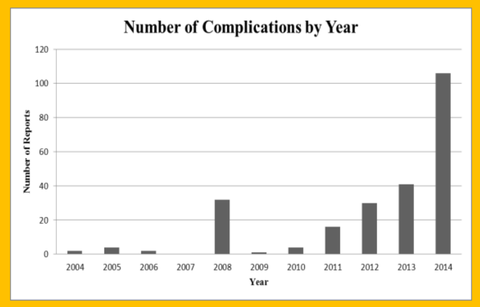

Figure 3

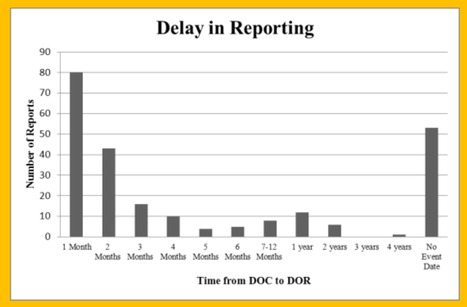

Figure 4

Discussion

A major limitation of MAUDE for OAI-related complications is the disparate reporting and overall lack of uniformity making classification difficult. When a report is made to MAUDE, the reporter enters free text about the event and submits it. The result is a range between vague and useless words to overly detailed and extensive information in any given report. We experienced difficulty in classification which resulted in the formation of as many as 7 subcategories within a category.

The current study found implant loss as the most commonly reported complication within the database. This contrasts many other reports where implant loss was fairly uncommon compared to other complications[4,5]. Likewise, in these same studies (and in the senior authors experience), skin reactivity issues are the most prevalent complications seen in OAIs, however, MAUDE reports of skin issues are a distant second place. This difference in the relative incidence of complications between reality and the database is misleading, and is likely due to reporting bias. As skin reactions are relatively commonplace with most easily managed in the office, most surgeons may not consider one *sufficiently* adverse to necessitate a report to the manufacturer and/or a federal database. This may be related to who is reporting the complication.

MAUDE does not directly differentiate between mandatory and voluntary reporters. Industry and patients may have divergent ideas of what constitutes a serious adverse event (SAE). Reports such as “patient feeling ill to upper respiratory illness and suspects the implant” do not constitute a SAE, and was therefore likely entered by a voluntary reporter. The more technically specific reports may have been submitted by industry, though as in the example above, there is no way to know for sure. Since no unique case identifiers are included in reports, it is conceivable that both mandatory and voluntary reporters are submitting entries for the same complication.

Another of the more substantial shortcomings of MAUDE is its failure to include the *total* number of OAIs placed (devices placed with *and without* complications). Without this denominator, only relative comparisons of values within the MAUDE data set can be determined and prevalence cannot be known. Without the context of total numbers of OAIs placed over a given timeframe, MAUDE searchers could misinterpret the data. Potential candidates may inaccurately conclude that, based on the number of reports, one manufacturer has a higher rate of complications than others. In fact, this is simply unknown. Despite disclaimers to the contrary on the MAUDE website, the casual searcher of this database may inaccurately conclude that complications are due to a fault with the product itself – whereas in reality, given the ability for anyone to report “complications,” device users themselves may have caused or contributed to the complications.

Although the FDA approved OAIs in 1996[14], the first report is not found until 2003. The reasons for this are unclear. The reason for a spike in 2008 is also unclear. Mandatory reporters are required by law to input the data within 30 days, however, industry representatives may not be aware of a particular complaint or complication for months after it occurs. Moreover, every manufacturer may have their own threshold for what constitutes a SAE, and these may change over time. Fears of additional regulatory scrutiny may prompt manufacturers to set the bar for reports even lower.

Conclusion

MAUDE lacks uniformity among reports making categorization difficult, does not differentiate between mandatory and voluntary reporters which may result redundant reporting, and does not provide a total number of implants placed, meaning that only relative and not overall rates of complications can be estimated. Given the delay in reporting and the inconsistency of reports per year, there can be no confidence that all reports are accounted for at any point in time. Trends that could be observed from what reports are left cannot therefore be trusted. Simply put MAUDE is questionable at best in its usefulness as a public database and falls short of its utility.

References

1. Gluth MB, Eager KM, Eikelboom RH, et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. Otol Neurotol. 2010 Dec;31(9): 1427–34. doi: 10.1097/MAO.0b013e31f1f0c53e
2. Reyes RA, Tjellström A, Granström G. Evaluation of implant losses and skin reactions around extraoral bone-anchored implants: A 0- to 8-year follow-up. Otolaryngol Head Neck Surg. 2000 Feb;122(2):272-6. doi: 10.1016/S0194-5998(00)70255-5
3. Faber HT, de Wolf MJ, de Rooy JW, et al. Bone-anchored hearing aid implant location in relation to skin reactions. Arch Otolaryngol Head Neck Surg. 2009 Aug;135(8):742-7. doi: 10.1001/archoto.2009.99
4. MAUDE–Manufacturer and User Facility Device Experience [Food and Drug Administration website]. n.d. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Accessed Jan 1, 2015.
5. Friedman DC, Lensvay TS, Hanasoged B. Instrument Failures for the da Vinci Surgical System: a Food and Drug Administration MAUDE Database Study. Surg Endosc. 2013 May;27(5):1503-8. doi: 10.1007/s00464-012-2659-8
6. Badia CD, Nyirjesy P, Atogho A. Endometrial ablation devices: review of a manufacturer and user facility device experience database. J Minim Invasive Gynecol. 2007 Jul-Aug;14(4):436-41. doi: http://dx.doi.org/10.1016/j.jmig.2007.05.008
7. Tremaine AM, Avram MM. FDA MAUDE data on complications with lasers, light sources, and energy-based devices. Lasers Surg Med. 2015 Feb;47(2):133-40. doi: 10.1002/lsm.22328
8. DeLuca LA Jr, Simpson A, Beskind D, et al. Analysis of automated external defibrillator device failures reported to the Food and Drug Administration. Ann Emerg Med. 2012 Feb;59(2):103-11. doi: http://dx.doi.org/10.1016/j.annemergmed.2011.07.022
9. Chatterjee S, Herrmann HC, Wilensky RL, et al. Safety and Procedural Success of Left Atrial Appendage Exclusion With the Lariat Device: A Systematic Review of Published Reports and Analytic Review of the FDA MAUDE Database. JAMA Intern Med. 2015 July; 175(7): 1104. doi: 10.1001/jamainternmed.2015.1513.
10. Andreoli JM, Lewandowski RJ, Vogelzang RL, Ryu RK. Comparison of complication rates associated with permanent and retrievable inferior vena cava filters: a review of the MAUDE database. J Vasc Interv Radiol. 2014 Aug;25(8):1181-5. doi: http://dx.doi.org/10.1016/j.jvir.2014.04.016
11. Causon A, Verschuur C, Newman TA. Trends in cochlear implant complications: implications for improving long-term outcomes. Otol Neurotol. 2013 Feb;34(2):259-65. doi: 10.1097/MAO.0b013e31827d0943
12.. Tambyraja RR, Gutman MA, Megerian CA. Cochlear implant complications: utility of federal database in systematic analysis. Arch Otolaryngol Head Neck Surg. 2005 Mar;131(3):245-50. doi: 10.1001/archotol.131.3.245.
13. 510(k) Premarket Notification [Food and Drug Administration website]. n.d. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K955713. Accessed June 23, 2015.