MRI-Related Adverse Events for Cochlear Implants: A MAUDE Database Study

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Abstract

Introduction: Evaluation of cochlear implant (CI) adverse event reports (AERs) related to magnetic resonance imaging.

Methods: Retrospective review of CI records from the MAUDE database between 1 January 2014 to 31 December 2023. MRI-related AERs were identified using keyword searches. Data was organized according to year and manufacturer: Manufacturer A (Cochlear Limited), Manufacturer B (Med-El) and Manufacturer C (Advanced Bionics). Records were further subclassified by adverse event type and device model. Analysis of data was performed using descriptive and inferential statistics.

Results: 780 AERs were identified across all three manufacturers and represent 3.9% of total reports from Manufacturer A, 0.13% of reports from Manufacturer B, and 1.2% of reports from Manufacturer C. The most frequent adverse events identified included: magnet dislodgement during MRI (84.5%), pain during/following MRI (6.9%), and flipped magnet/reversed polarity (4.2%). 14% of AERs indicated that proper device-related MRI precautions were not followed when patients underwent imaging. Negative binomial regression showed an average yearly increase of 13% (95% confidence interval, 2%-25%) in the share of MAUDE MRI-related AERs across all manufacturers (p=0.019).

Conclusion: Analysis of MAUDE AERs can highlight noteworthy trends and reinforce the importance of clear and proper MRI guidelines for the cochlear implant population. Definitive conclusions regarding manufacturer safety and accuracy of figures must be approached with caution given the often-incomplete and limited nature of MAUDE data.

Introduction

- MRI is a cornerstone in modern medical diagnostics and research. Some of its benefits include its non-invasiveness, versatility, and detailed soft-tissue imagery without ionizing radiation.[1]
- Given these benefits, the use of MRI has increased in recent years in both children and adults.[2]
- Cochlear implantation has also significantly increased in recent years, and eligibility criteria has expanded to include more conditions including single-sided deafness and asymmetric hearing impairment.[3-4]
- MRI is contraindicated with ferromagnetic material, which includes the subcutaneous internal magnet found in cochlear implants (CI) that is required for proper device functioning.
- FDA-approval of diametric magnet CIs was in 2015, and these newer models have been associated with significantly lower MRI-related adverse event risks.[5](fig. 1)
- However, a significant portion of the CI population continues to use older, legacy model CIs. The elevated risk of MRI-related adverse events persists for these patients.[6]
- Common MRI-related adverse events for legacy CI users include: pain, magnet dislocation/displacement, device malfunction, edema, infection, etc.
- Legacy CI users are also subject to additional precautions during MRI to help ensure safety. However, recent data has shown concerning indications that adherence to proper MRI protocol for legacy CI users may be decreasing.[6]

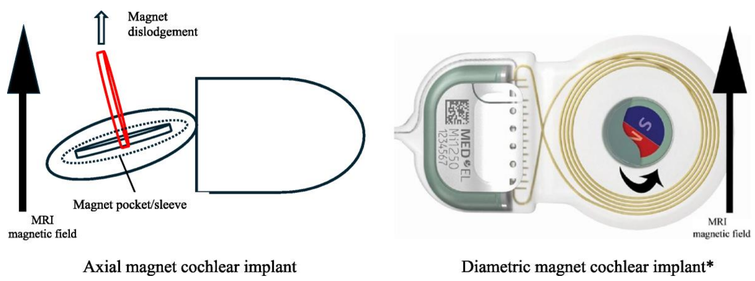

Figure 1. Axial magnet vs diametric magnet in MRI magnetic field. Adapted from Lu et al. (7).

Methods and Materials

- Retrospective review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.
- Database filters were used to extract all MAUDE cochlear implant data from 1 January 2014 to 31 December 2023.
- Data was categorized by manufacturer: Manufacturer A (Cochlear Ltd), Manufacturer B (Med-El), and Manufacturer C (Advanced Bionics).
- Keyword searches were used to identify all AERs potentially related to MRI.
- All relevant AERs were thoroughly reviewed and categorized according to adverse event type.
- MRI-Related AERs were reviewed for indication of improper imaging precaution adherence.
- Negative binomial regression was used to analyze any longitudinal change in MRI-related AERs over the specified timeframe.

Results

- 780 MRI-related, cochlear implant AERs were identified across all three manufacturers during the specified timeframe.
- These AERs represent 3.9% of total reports from Manufacturer A, 0.13% from Manufacturer B, and 1.2% from Manufacturer C.
- 14% of MRI-related AERs indicated that proper device-related MRI precautions (eg, head wrapping) were not followed when patients underwent imaging. (fig. 2)
- The most frequent primary adverse events identified included:
  - Magnet dislodgement during MRI (84.5%)
  - Pain during/following MRI (6.9%)
  - Flipped magnet/reversed polarity (4.2%)
  - Other (4.4%) (fig. 3)
- Regression analysis showed an average yearly increase of 13% (95% CI, 2%-25%) in the share of MAUDE CI AERs for MRI-related adverse events (p=0.019). (fig. 4)

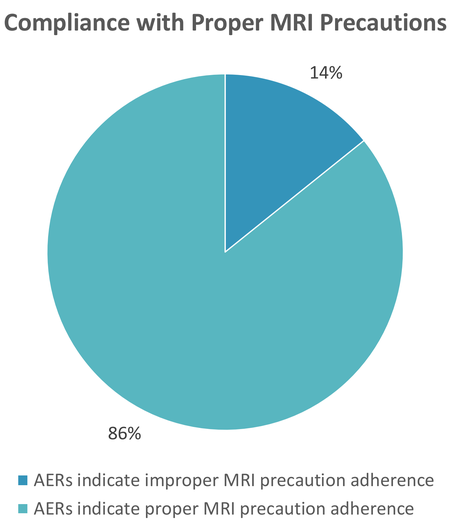

Figure 2. Distribution of MAUDE MRI-Related CI AERs, breakdown by reported proper MRI precaution adherence.

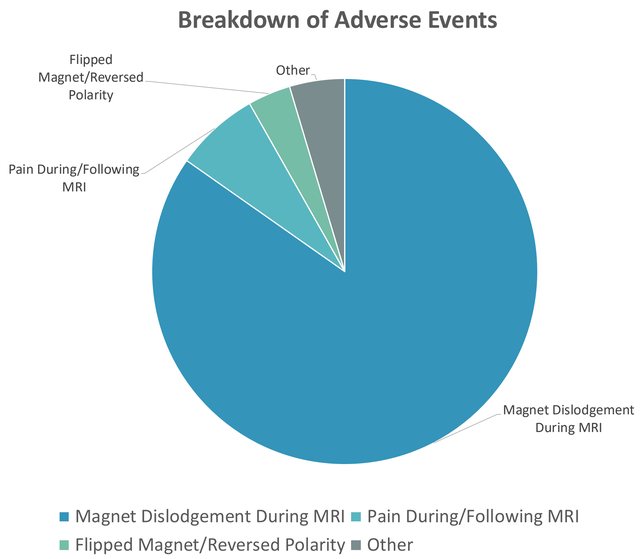

Figure 3. Distribution of MAUDE MRI-Related CI AERs, breakdown by adverse event type.

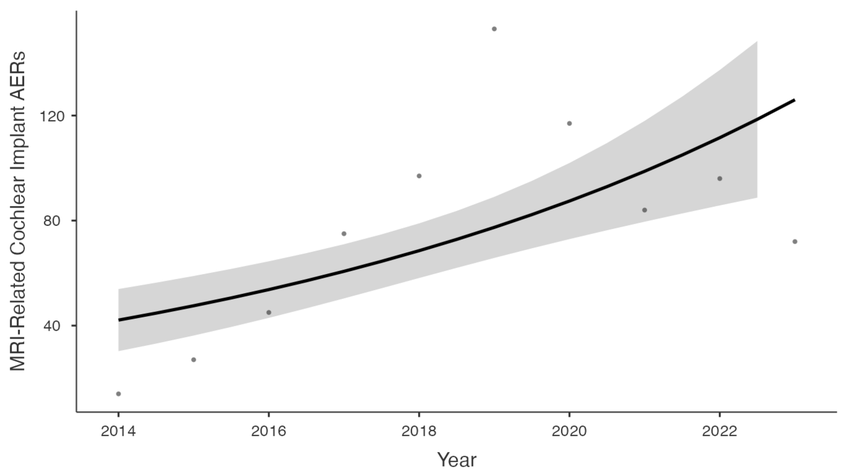

Figure 4. Average yearly increase of 13% in share of MAUDE CI AERs for MRI-related adverse events.

Conclusions

- Although MRI-related adverse events for cochlear implants have decreased since the introduction of diametric magnet device models, a sizeable portion of the cochlear implant population continues to use legacy, axial magnet devices.
- The risks associated with adverse events persist for this patient population, as do the necessary additional precautions for MRI procedures.
- Recent data has suggested that adherence to these precautions has been decreasing, potentially introducing additional, unnecessary harm to legacy CI users who require MRI imaging.
- More research may be warranted to identify whether proper protocol adherence is decreasing in clinical practice.
- Our data is limited, as are all MAUDE studies, and cannot be used to make generalizable conclusions that extend beyond the confines of the database itself.

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